

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT PURSUANT TO  
SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: November 8, 2022  
(Date of earliest event reported)

ANAPTYSBIO, INC.  
(Exact Name of Registrant as Specified in Charter)

Delaware  
(State or Other Jurisdiction of Incorporation)

001-37985  
(Commission File Number)

20-3828755  
(IRS Employer Identification No.)

10770 Wateridge Circle, Suite 210,  
San Diego, CA 92121  
(Address of Principal Executive Offices, and Zip Code)

(858) 362-6295  
(Registrant's Telephone Number, Including Area Code)

Not Applicable  
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ANAB	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02 Results of Operations and Financial Condition.**

On November 8, 2022, AnaptysBio, Inc. (“AnaptysBio”) issued a press release announcing its financial results for the three and nine months ended September 30, 2022. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02, including Exhibit 99.1 to this Current Report on Form 8-K, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any registration statement or other document filed by AnaptysBio with the Securities and Exchange Commission, whether made before or after the date of this Current Report on Form 8-K, regardless of any general incorporation language in such filing (or any reference to this Current Report on Form 8-K generally), except as shall be expressly set forth by specific reference in such filing.

**Item 7.01. Regulation FD.**

On November 8, 2022, AnaptysBio updated its corporate investor presentation, a full copy of which is attached hereto as Exhibit 99.2.

The information in this item 7.01, including Exhibit 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Exchange Act or Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits

**Exhibit Number****Exhibit Title or Description**

[99.1](#)

Press release issued by AnaptysBio, Inc. regarding its financial results for the three and nine months ended September 30, 2022, dated November 8, 2022.

[99.2](#)

AnaptysBio Corporate Overview November 2022.

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Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document).

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 8, 2022

AnaptysBio, Inc.

By: /s/Dennis Mulroy

Name: Dennis Mulroy

Title: Chief Financial Officer

## AnaptysBio Announces Third Quarter 2022 Financial Results and Provides Pipeline Update

- Anticipate Rosnilimab, our anti-PD-1 agonist antibody, top-line data in the ongoing AZURE Phase 2 trial in moderate-to-severe alopecia areata in Q1 2023
- Anticipate ANB032, our anti-BTLA agonist antibody, U.S. IND submission for a Phase 2 trial in Q4 2022
- Announced our third wholly owned immune cell modulator program, ANB033, our anti-CD122 antagonist antibody, with a U.S. IND submission for a Phase 1 trial in 1H 2024
- Sold our interest in future Zejula royalties to a wholly-owned subsidiary of DRI Healthcare Trust for up to \$45 million during Q3 2022

**SAN DIEGO, November 8, 2022** - AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics, today reported operating results for the third quarter ended September 30, 2022 and provided pipeline updates.

“We are excited about the potential of our novel immune cell modulator pipeline, including our two checkpoint agonists in clinical-stage development, rosnilimab and ANB032. We believe their mechanisms of action, acting directly on cell types mediating disease pathology, have the potential to treat a broad range of autoimmune and inflammatory disorders” said Daniel Faga, interim president and chief executive officer of AnaptysBio. “We’re well capitalized to execute with over \$590 million in cash at the end of Q3 as we move forward in our strategic portfolio review.”

### Rosnilimab (Anti-PD-1 agonist) Program

- Rosnilimab, our investigational wholly owned anti-PD-1 agonist antibody, is in the ongoing AZURE Phase 2 clinical trial in moderate-to-severe alopecia areata, and we anticipate top-line data in Q1 2023.

### ANB032 (Anti-BTLA agonist) Program

- ANB032, our investigational wholly owned anti-BTLA agonist antibody, will be advancing with a U.S. IND submission for an initial Phase 2 clinical trial in Q4 2022.

### ANB033 (Anti-CD122 antagonist) Program

- ANB033, our investigational wholly owned anti-CD122 antagonist antibody, targets the common beta subunit shared by the IL-15 and IL-2 receptors. IL-15 signaling mediates the survival and maintenance of tissue resident memory T cells (T<sub>RM</sub>). The presence of long-lived and persistent T<sub>RM</sub> have been shown to drive tissue-specific immune-mediated inflammation. We anticipate submitting a U.S. IND in first half of 2024.

### Imsidolimab (Anti-IL-36 receptor) Program

- Imsidolimab, our investigational wholly owned anti-IL-36R therapeutic antibody, is in Phase 3 trials in generalized pustular psoriasis (GPP), and we anticipate top-line data from the GEMINI-1 Phase 3 clinical trial in Q4 2023 and plan to outlicense imsidolimab prior to potential FDA approval.

### GSK Partnered Programs

- PERLA, a head-to-head Phase 2 trial of JEMPERLI (dostarlimab) vs. Keytruda in patients with metastatic non-squamous non-small cell lung cancer met its primary endpoint of objective response rate (ORR) of dostarlimab plus chemotherapy versus pembrolizumab plus chemotherapy as assessed by blinded independent central review per RECIST v1.1.
  - GSK will present full results, including the primary endpoint of ORR and the key secondary endpoint of progression-free survival, at the ESMO Immuno-Oncology Annual Congress on Friday, December 9<sup>th</sup>.
- COSTAR, a Phase 2 trial of dostarlimab plus cobolimab, an anti-TIM-3 antagonist antibody, achieved pre-specified efficacy and safety criteria, and GSK is advancing both arms of the COSTAR Lung clinical trial

from Phase 2 to Phase 3, testing both doublet and triplet combinations of dostarlimab plus chemotherapy, and cobolimab plus dostarlimab plus chemotherapy in advanced non-small cell lung cancer who have progressed on prior anti-PD-(L)1 therapy and chemotherapy.

- Cobolimab was discovered at AnaptysBio and licensed to TESARO, Inc., (GSK) as part of the same collaboration agreement as dostarlimab.
- AnaptysBio earned a \$5 million milestone from GSK in October 2022 on initiation of the first Phase 3 trial with cobolimab.
- Sold our royalty interest on future global net sales of Zejula to a wholly-owned subsidiary of DRI Healthcare Trust for up to \$45 million during Q3.
  - Received an upfront payment of \$35 million and are eligible for a further \$10 million from DRI upon FDA approval of Zejula for the treatment of endometrial cancer, for which the drug is currently in a fully-enrolled ongoing Phase 3 study, to the extent that such approval occurs on or before December 31, 2025.

#### Third Quarter Financial Results

- Cash, cash equivalents and investments totaled \$590.5 million as of September 30, 2022, compared to \$615.2 million as of December 31, 2021, for a decrease of \$24.7 million. The decrease relates primarily to cash used for operating activities offset by cash received from the Zejula royalty sale and stock option exercises.
- Collaboration revenue was \$1.3 million and \$3.5 million for the three and nine months ended September 30, 2022, compared to \$20.9 million and \$62.2 million for the three months and nine months ended September 30, 2021. The decrease relates primarily to one development milestone achieved for JEMPERLI for the three months ended September 30, 2021, and four development milestones achieved for JEMPERLI for the nine months ended September 30, 2021, and no development milestones achieved during the nine months ended September 30, 2022.
- Research and development expenses were \$22.1 million and \$65.4 million for the three and nine months ended September 30, 2022, compared to \$22.2 million and \$71.7 million for the three and nine months ended September 30, 2021. The year-to-date decrease was due primarily to reduced clinical costs and manufacturing costs for the Company's programs. The R&D non-cash, stock-based compensation expense was \$1.5 million and \$5.0 million for the three and nine months ended September 30, 2022, as compared to \$1.8 million and \$4.4 million in the same period in 2021.
- General and administrative expenses were \$8.9 million and \$27.2 million for the three and nine months ended September 30, 2022, compared to \$5.4 million and \$16.1 million for the three and nine months ended September 30, 2021. The increase was due primarily to \$3.8 million of costs incurred from personnel changes in the first quarter of 2022 and non-cash stock compensation expense. The G&A non-cash, stock-based compensation expense was \$4.7 million and \$15.7 million for the three and nine months ended September 30, 2022, which includes \$3.2 million of the \$3.8 million one-time costs described earlier as compared to \$2.6 million and \$7.0 million in the same period in 2021.
- Net loss was \$33.5 million and \$102.3 million for the three and nine months ended September 30, 2022, or a net loss per share of \$1.18 and \$3.64, compared to a net loss of \$6.7 million and \$25.3 million for the three and nine months ended September 30, 2021, or a net loss per share of \$0.24 and \$0.92.

#### **About AnaptysBio**

AnaptysBio is a clinical-stage biotechnology company focused on delivering innovative immunology therapeutics. We are developing immune cell modulators, including two checkpoint agonists in clinical-stage development, for autoimmune and inflammatory disease: rosnilimab, our anti-PD-1 agonist program in Phase 2 for the treatment of moderate-to-severe alopecia areata; and ANB032, our anti-BTLA agonist program. AnaptysBio is also developing insidolimab, our anti-IL-36R antibody in Phase 3 for the treatment of generalized pustular psoriasis, or GPP. We also have additional preclinical programs and discovery research of potentially innovative immunology therapeutics, including ANB033, an anti-CD122 antagonist antibody for the treatment of inflammatory diseases.

AnaptysBio has also developed multiple therapeutic antibodies in an immuno-oncology collaboration with GSK, including an anti-PD-1 antagonist antibody (JEMPERLI (dostarlimab-gxly)), an anti-TIM-3 antagonist antibody (cobolimab, GSK4069889) and an anti-LAG-3 antagonist antibody (GSK4074386).

#### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the timing of the release of data from our clinical trials, including imsidolimab's Phase 3 clinical trial in GPP and rosnilimab's Phase 2 clinical trial in alopecia areata; and the timing of ANB032's IND filing for a Phase 2 clinical trial and the timing of ANB033's IND filing; our ability to find a licensing partner for imsidolimab and the timing of any such transaction; and our projected use of our cash resources. Statements including words such as "plan," "continue," "expect," or "ongoing" and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause the company's actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company's ability to advance its product candidates, obtain regulatory approval of and ultimately commercialize its product candidates, the timing and results of preclinical and clinical trials, the company's ability to fund development activities and achieve development goals, the company's ability to protect intellectual property and other risks and uncertainties described under the heading "Risk Factors" in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

#### **Contact:**

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AnaptysBio, Inc.  
858.732.0201  
[dmulroy@anaptysbio.com](mailto:dmulroy@anaptysbio.com)

**AnaptysBio, Inc.**  
**Consolidated Balance Sheets**  
(in thousands, except par value data)  
(unaudited)

	September 30, 2022	December 31, 2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 58,547	\$ 495,729
Receivables from collaborative partners	1,180	876
Short-term investments	384,419	52,368
Prepaid expenses and other current assets	6,298	4,903
Total current assets	450,444	553,876
Property and equipment, net	1,972	2,283
Operating lease right-of-use assets	18,320	19,558
Long-term investments	147,511	67,097
Other long-term assets	256	256
Total assets	<u>\$ 618,503</u>	<u>\$ 643,070</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,006	\$ 1,741
Accrued expenses	16,453	12,853
Current portion of operating lease liability	1,604	1,505
Total current liabilities	21,063	16,099
Liability related to sale of future royalties	301,586	251,093
Operating lease liability, net of current portion	18,235	19,450
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Common stock, \$0.001 par value, 500,000 shares authorized, 28,354 shares and 27,647 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	28	28
Additional paid in capital	707,662	678,575
Accumulated other comprehensive loss	(6,007)	(422)
Accumulated deficit	(424,064)	(321,753)
Total stockholders' equity	277,619	356,428
Total liabilities and stockholders' equity	<u>\$ 618,503</u>	<u>\$ 643,070</u>

**AnaptysBio, Inc.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except per share data)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	\$ 1,293	\$ 20,890	\$ 3,479	\$ 62,164
Operating expenses:				
Research and development	22,064	22,221	65,424	71,720
General and administrative	8,862	5,432	27,236	16,101
Total operating expenses	30,926	27,653	92,660	87,821
Loss from operations	(29,633)	(6,763)	(89,181)	(25,657)
Other income (expense), net:				
Interest income	2,262	64	3,711	363
Non-cash interest expense for the sale of future royalties	(6,135)	—	(16,857)	—
Other income, net	4	33	16	36
Total other income (expense), net	(3,869)	97	(13,130)	399
Net loss	(33,502)	(6,666)	(102,311)	(25,258)
Unrealized loss on available for sale securities	(2,146)	(24)	(5,585)	(196)
Comprehensive loss	\$ (35,648)	\$ (6,690)	\$ (107,896)	\$ (25,454)
Net loss per common share:				
Basic and diluted	\$ (1.18)	\$ (0.24)	\$ (3.64)	\$ (0.92)
Weighted-average number of shares outstanding:				
Basic and diluted	28,289	27,436	28,071	27,397





## Corporate Overview

*November 2022*



Nasdaq: ANAB



## Safe Harbor Statement



This presentation and any accompanying oral presentation contain “forward-looking” statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to: the timing of the release of data from our clinical trials, including imsidolimab’s Phase 3 trial in GPP and rosnilimab’s Phase 2 trial in alopecia areata; timing of an IND filing for ANB032; timing of initiation of ANB032’s Phase 2 trial; timing of an IND filing for ANB033; the predicted mechanisms of action of our drug candidates; expectations regarding the commercial potential and anticipated peak annual global sales of JEMPERLI, the timing and potential amount of milestones and royalty payments to be received under the GSK partnership and benefits expected from the agreements with Sagard and DRI Healthcare Trust; and our projected 2022 operating expenditure. Statements including words such as “plan,” “continue,” “expect,” or “ongoing” and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they do not fully materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that may cause the company’s actual activities or results to differ significantly from those expressed in any forward-looking statement, including risks and uncertainties related to the company’s ability to advance its product candidates, obtain regulatory approval of and ultimately commercialize its product candidates, the timing and results of preclinical and clinical trials, the company’s ability to fund development activities and achieve development goals, the company’s ability to protect intellectual property and other risks and uncertainties described under the heading “Risk Factors” in documents the company files from time to time with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this presentation, and the company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

Certain information contained in this presentation may be derived from information provided by industry sources. The Company believes such information is accurate and that the sources from which it has been obtained are reliable. However, the Company cannot guarantee the accuracy of, and has not independently verified, such information.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

# AnaptysBio

Wholly owned immune cell modulating antibodies may restore immune balance across moderate-to-severe complex diseases



## Two Clinical-Stage Checkpoint Agonists

- **Rosnilimab, PD-1 agonist:** P2a top-line data in alopecia areata Q1 2023
- **ANB032, BTLA agonist:** P2 trial (indication undisclosed) to initiate H1 2023
- Potential applicability to broad range of autoimmune and inflammatory disorders including dermatological, rheumatology and gastroenterology

## Immune Cell Modulator Preclinical Portfolio

- **ANB033, CD122 antagonist:** IND submission H1 2024
- Deep immunology pipeline of immune cell modulators on high-impact targets

## Imsidolimab (IL-36R antagonist)

- Registration-enabling top-line data in GPP in Q4 2023
- *Program to be out-licensed prior to FDA Approval*

## Significant Royalties from GSK I-O Financial Collaboration

- JEMPERLI (PD-1 antagonist) 8-25% royalties plus milestones\*;
- P3 readouts in 1L endometrial (Q4:22) and 1L ovarian (2H:23)
- TIM-3 and LAG-3 oncology antagonists: 4-8% royalties plus milestones

## Strong Capital Position

- >\$590mm in cash and equivalents as of Q3 2022
- Anticipate 2022 full year operating expenditure of \$90 to \$100 million

\* Royalties and milestones on JEMPERLI net sales <\$1bn revert to Sagard until paydown complete of non-recourse capped monetization transaction.

## Multiple Clinical-Stage Catalysts Through 2023

Additional trial initiations within next 12 months for both checkpoint agonists across dermatological, rheumatology and gastroenterology therapeutic areas

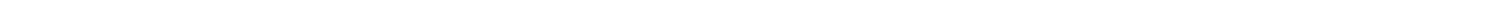


Antibody Program	Therapeutic Indication	Development Stage & Anticipated Milestones				
		Lead Optimization	IND - Enabling	Phase 1	Phase 2	Phase 3
Imsidolimab (ANB019): Anti-IL-36R	Generalized Pustular Psoriasis	[Progressing through Lead Optimization, IND - Enabling, Phase 1, and Phase 2]				Top-Line Data Q4 2023
Rosnilimab (ANB030): Anti-PD-1 Agonist	Alopecia Areata	[Progressing through Lead Optimization, IND - Enabling, and Phase 1]			AZURE: Top-Line Data Q1 2023	
ANB032: Anti-BTLA Agonist	Inflammatory Diseases	[Progressing through Lead Optimization, IND - Enabling, and Phase 1]			IND Q4 2022; Initiate Phase 2 Trial H1 2023	
ANB033: Anti-CD122 Antagonist	Inflammatory Diseases	[Progressing through Lead Optimization]	IND Submission H1 2024			

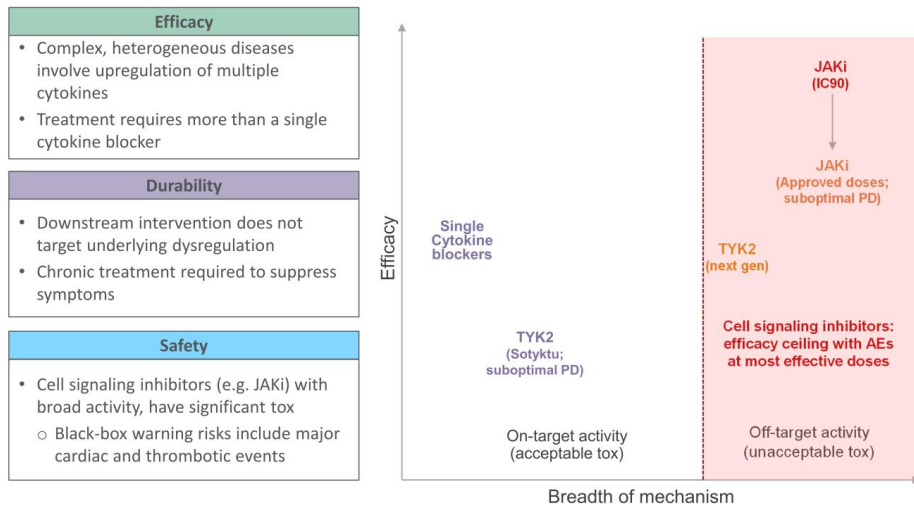
Wholly owned portfolio developed internally using our proprietary antibody platform technology



**Advantages of Immune Cell Modulation in  
Treatment of Inflammatory Diseases**



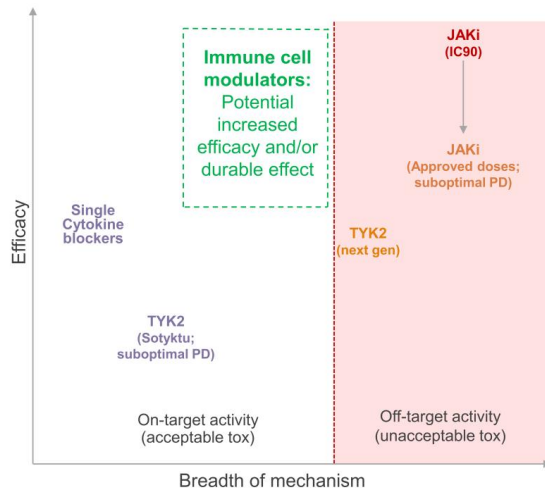
# Moderate-to-Severe Inflammatory Diseases are Complex Leading to Shortcomings in SoC Therapies



# Immune Cell Modulators May Restore Immune Balance Across Moderate-to-Severe Complex Diseases



<b>Efficacy: Act directly on dysregulation</b>
<ul style="list-style-type: none"> <li>Suppression of immune cells may increase breadth of response</li> </ul>
<b>Durability: Longer remission</b>
<ul style="list-style-type: none"> <li>Restore tolerance by modulating key immune cell types</li> <li>Potential for durable response</li> </ul>
<b>Safety: Targeting immune cells</b>
<ul style="list-style-type: none"> <li>Preferential target expression on activated immune cells may enable wider therapeutic window</li> <li>Growing agonist class experience has been well-tolerated to date</li> <li>No evidence of carcinogenicity with checkpoint inhibitors in I&amp;I, such as abatacept, in decades of use</li> </ul>



# Immune Cell Modulators are a Novel Therapeutic Class

Suppress activated immune cell types to restore immune balance



		Anaptys Immune Cell Modulators			Potential mechanisms of action
		Rosnilimab (anti PD-1 agonist)	ANB032 (anti-BTLA agonist)	ANB033 (CD122 antagonist)	
Adaptive Immunity	Treg/Tcon ratio	↑	↑	↑	<ol style="list-style-type: none"> <li>Bias Treg/Tcon ratio towards tolerance at sites of aberrant inflammation and systemically</li> <li>Modulation of adaptive immunity may enable resolution of inflammatory cycle</li> </ol>
	Tcon (Activated PD-1+ T cells)	↓	↓		
	Trm	↓		↓	
	B cells		↓		
Innate Immunity	NK cells		↓	↓	<ol style="list-style-type: none"> <li>Modulation of innate immunity may support return to homeostasis</li> <li>Potential to deplete (rosnilimab) or induce death (ANB033) in pathogenically targeted activated cells</li> </ol>
	Dendritic cells		↓		
	ILCs	↓			
ADCC (Fc region)		Depletion potential (IgG1)	Non-depleting (IgG4)	Non-depleting (undisclosed)	

Note: Ongoing immunophenotyping will further inform understanding of ANAB immune cell modulator mechanisms of action.



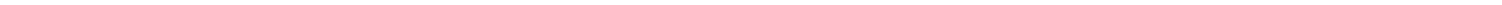
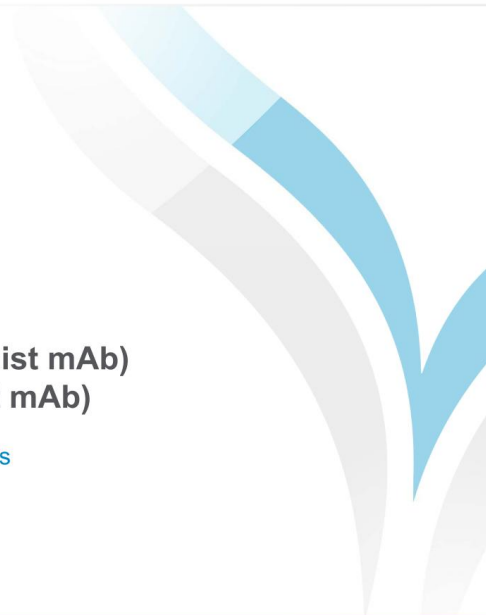


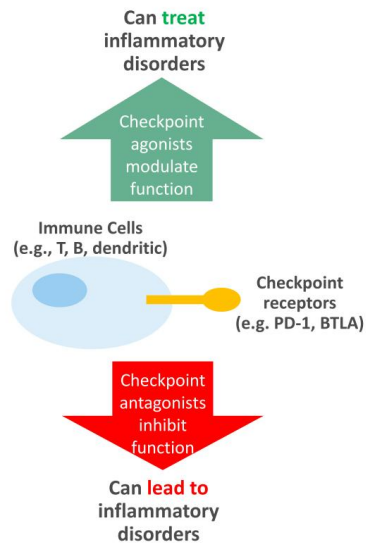
**Checkpoint Agonists:**

**Rosnilimab (Anti-PD-1 agonist mAb)**

**ANB032 (Anti-BTLA agonist mAb)**

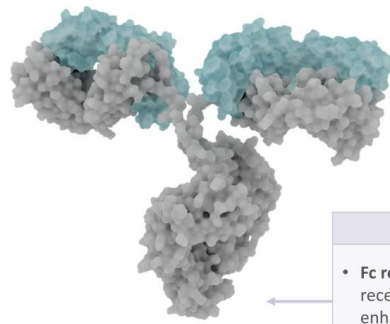
Autoimmune and Inflammatory Diseases





- Potent checkpoint agonists for PD-1 and BTLA down regulate T cell mediated immune responses
  - BTLA also present on B cells and dendritic cells
- Potential applicability across moderate-to severe complex diseases
  - Dermatology: alopecia areata, vitiligo, atopic dermatitis and psoriasis
  - Rheumatology: RA and SLE
  - Gastroenterology: UC and CD
  - Respiratory and Neurology
  - Potential for concomitant or sequential combination with targeted immune-suppressive therapies

# Characteristics and Potential Differentiation of Agonist Antibodies



## CDR characteristics

- **Binding epitope:**
  - Agonists bind epitope on opposing face to spare interaction and suppressive activity of natural ligands (e.g. PD-L1 and HVEM)
  - Binding near cell membrane to enhance agonistic signaling
- **Binding affinity:** Affinity tuned to optimize agonism, unlike for antagonists where affinity is maximized

## Fc characteristics

- **Fc receptor-assisted clustering:** Fc region affinity to Fc receptors impacts efficiency of receptor clustering to enhance agonistic signaling
- **Effector function:** Isotype selection and Fc modifications to effect ADCC as desired

## In vitro and in vivo assay-based optimization

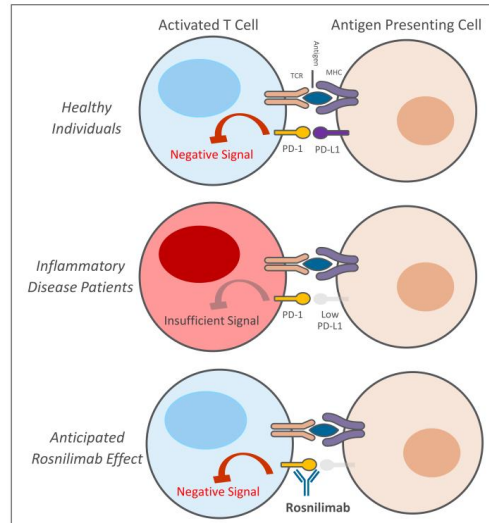
- Iterative assay-quantified functional activity is critical to selecting the most potent agonist across interactions of CDR and Fc characteristics

## Rosnilimab (ANB030): Anti-PD-1 Agonist Antibody

Suppression of T cell mediated inflammatory diseases

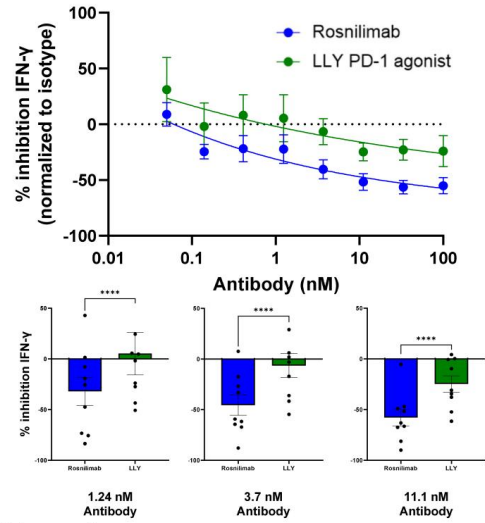


- Rosnilimab: IgG1 antibody that binds to PD-1+ T cells designed to induce:
  - **Agonistic signaling:** Mimic PD-L1 function to down-regulate T cell activity in inflamed tissues
  - **Depletion:** Eliminate PD-1+ T cells in inflamed tissue and peripheral circulation via effector function
- Rosnilimab has the potential to suppress and drive long-term modification of T cell driven inflammatory immune responses



# Rosnilimab Significantly Reduces IFN $\gamma$ in Health Donor PBMCs

- Rosnilimab shows meaningful IFN $\gamma$  inhibition beginning at low concentrations
- Differentiation from Lilly's PD-1 agonist sustained and deepens across clinical concentrations



Tetanus toxoid recall stimulation assay measures antigen-specific immune cell response. Prior immunity in majority of population due to tetanus vaccination.

# Rosnilimab Phase 1 Healthy Volunteer Trial Top-Line Data

*Favorable safety, pharmacokinetics and pharmacodynamic activity*



- 144 healthy volunteers in randomized, double-blind, placebo-controlled SAD and MAD cohorts
- Well tolerated with no dose-limiting toxicities
  - Most frequent AE was mild C-reactive protein increase in 9 (10%) rosnilimab patients and 1 (3.3%) severe event in placebo
  - SAEs only reported in SAD cohorts: 1 obstructive pancreatitis in placebo patient and 1 mild drug-unrelated COVID in rosnilimab patient
- Favorable PK with ~2 week half-life with IV or SC dosing

## Pharmacodynamic analysis:

- Full receptor occupancy observed during first week and maintained for 30 days
- Sustained reduction in PD-1+ peripheral T cells and antigen-specific *ex vivo* T cell function for 30 days

T Cell Population	Surface Markers	Average Change From Baseline
<b>Total T cells (Tcon and Treg)</b>	<b>CD3+</b>	<b>&lt;5% change</b>
Conventional T cells (Tcon)	CD3+, CD25low	<5% change
PD-1+ Tcon cells	CD3+, CD25low, PD-1+	50% reduction
<b>High PD-1+ Tcon cells</b>	<b>CD3+, CD25low, PD-1high</b>	<b>90% reduction</b>
<b>Total regulatory T cells (Treg)</b>	<b>CD3+, CD4+, CD25bright, CD127-</b>	<b>&lt;5% change</b>
Average change in T cell populations from baseline Shown at 400mg subcutaneous single dose cohort		

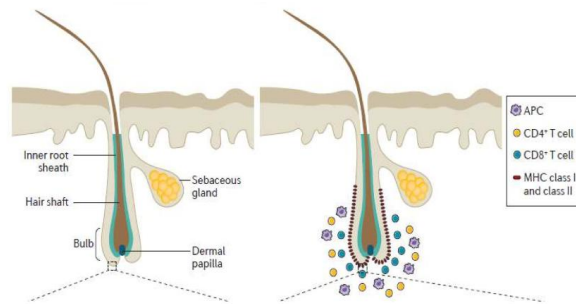
# Alopecia Areata is an Immune-Mediated Form of Hair Loss

*Inflammation-driven activation of antigen-specific PD-1+ T cells*



## Immune Privileged Healthy Hair Follicle

## Inflamed Hair Follicle in Alopecia Areata



- Stress event in immune privileged healthy hair follicle
- Potent immune response from keratinocyte-derived trichohyalin (TCHH) antigen specific cytokines
- Activated PD-1 high T cells expand to hair follicle and excessively secrete IFN $\gamma$  and other inflammatory cytokines
  - Drives aberrant MHC class I and class II expression
- Perpetual inflammatory cycle results in destruction of hair follicle cells & hair loss

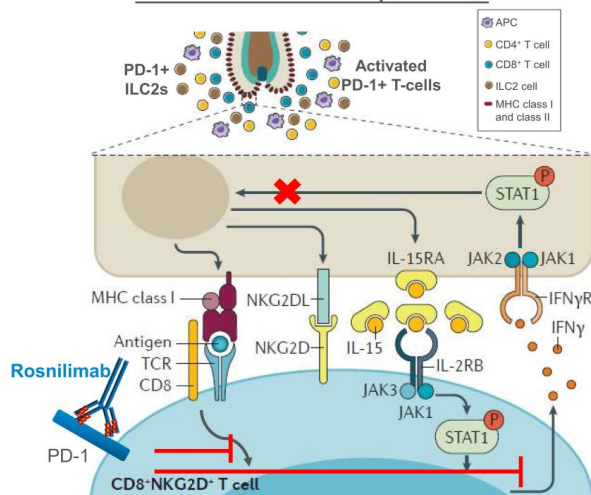
Adapted from Nat Rev Dis Primers. 2017 Mar 16; 3: 17011

## Rosnilimab Treatment for Alopecia Areata

Reduction, and potential elimination, of T cell activity may resolve the inflammatory cycle and reinitiate hair growth



### Inflamed Hair Follicle in Alopecia Areata

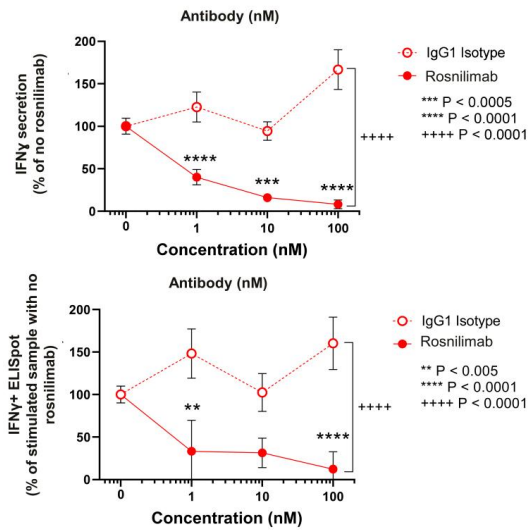


Adapted from Nat Rev Dis Primers. 2017 Mar 16; 3: 17011

- T cell deactivation may ameliorate IFN $\gamma$  driven MHC class I upregulation and antigen presentation
- Potentially contributes to resolution of hair follicle inflammatory cycle
- Rosnilimab binding results in:
  - Agnostic signaling of activated PD-1+ T cells in the hair follicle
    - Inhibit T cell expansion
    - Inhibit T cell IFN $\gamma$  secretion
  - IgG1 effector function depletion of activated PD-1+ T cells



## Rosnilimab Significantly Reduces IFN $\gamma$ in Alopecia Areata Patient PBMCs



- Alopecia areata patient PBMCs stimulated with TCHH peptide antigens
- Rosnilimab showed concentration dependent suppression of keratinocyte antigen-specific T cell expansion and IFN $\gamma$  secretion
- By disrupting antigen-specific T cell activity, rosnilimab may break the inflammatory cycle, restoring immune balance and reinitiating hair growth

## Rosnilimab May Show Differentiated Efficacy and Safety for the Treatment of Alopecia Areata

*"Proof-of-mechanism" P2a trial may inform development in additional diseases*



### Market Dynamics

- Up to ~1.5 million U.S. patients
  - >40% of patients estimated to have  $\geq$ 50% loss of scalp hair
- Chronic condition with substantial quality of life impact: depression, anxiety, other inflammatory conditions
- JAKi leave significant unmet need for patients with moderate-to-severe disease
  - Significant safety concerns: thrombosis and cardiac events
  - Durability of effect requires chronic (daily and continuous) treatment

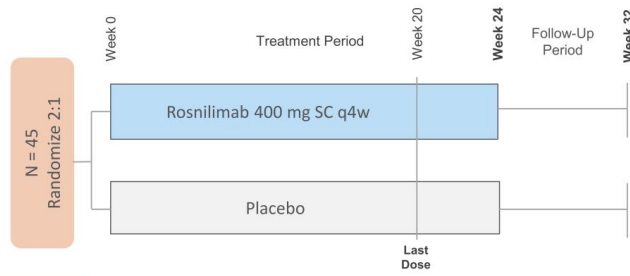
### Favorable Clinical Trial Attributes

- Antigen-specific T-cell driven disease
- Low and consistent placebo response rates for regulatory endpoint(s)
- Do not require concurrent alopecia areata treatment(s)

Source: NAAF, National Alopecia Areata Foundation, Benigno M. *Clinical, Cosmetic and Investigational Dermatology* 2020

# AZURE: Rosnilimab “Proof of Mechanism” Phase 2a Trial in Moderate-to-Severe Alopecia Areata

Top-line data Q1 2023



## “Proof of Mechanism” P2a data

- **Peripheral T cell effect**
  - Impact on activated T cells and Tcon / Treg ratio in blood and implications for broader inflammatory diseases through week 32
- **Change in SALT score (primary endpoint)**
  - Rate of SALT score change beyond last dose on week 20
- **Durability**
  - Maintenance of change in SALT score through week 32

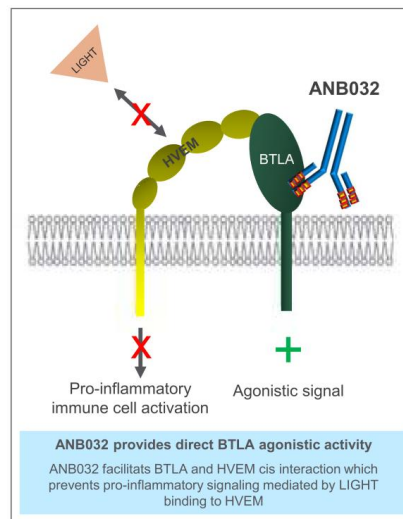
Population	<ul style="list-style-type: none"> <li>• Adult patients with moderate-to-severe alopecia areata</li> <li>• At least 50% scalp hair loss, as measured by SALT, for 6 months at baseline</li> </ul>	
Week 24 Endpoints	Primary	<ul style="list-style-type: none"> <li>• Change from Baseline in Severity of Alopecia Tool (SALT) Score</li> </ul>
	Secondary	<ul style="list-style-type: none"> <li>• Percentage change from baseline in SALT score</li> <li>• Proportion of subjects achieving a SALT score <math>\leq</math> 20</li> </ul>
Exploratory Endpoints	<ul style="list-style-type: none"> <li>• SALT change from baseline through week 32</li> <li>• Localized tissue PD: Scalp biopsy biomarkers (i.e. IFN<math>\gamma</math>, IL-15, T cell)</li> <li>• Systemic PD: Tcon and Treg</li> </ul>	

## ANB032: Anti-BTLA Agonist Antibody

P2 trial initiation (indication undisclosed) H1 2023; IND submission Q4 2022



- ANB032 is an IgG4 antibody that binds to BTLA in lymphoid (T and B) cells
  - BTLA also present on myeloid dendritic cells and required for Treg development
- ANB032 inhibits T cell proliferation and inflammatory cytokine secretion in patient-derived samples from numerous inflammatory diseases
- ANB032 demonstrated robust *in vivo* efficacy in animal models of GVHD
- Potential broad applicability to inflammatory disease due to breadth of BTLA expression across immune cell types

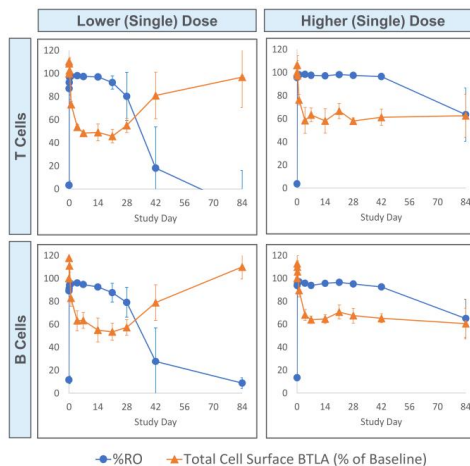


# ANB032 Phase 1 Healthy Volunteer Trial Top-Line Data

*Favorable safety, pharmacokinetics and pharmacodynamic activity*



- 96 healthy volunteers in randomized, double-blind, placebo-controlled SAD and MAD cohorts
- ANB032 well-tolerated with no dose limiting tox
  - Most AEs mild-to-moderate, of short duration, dose independent and resolved without sequelae
  - No Serious Adverse Events
- Favorable PK: ~2-week half-life with IV and SQ dosing
- Full receptor occupancy (RO) within hours and maintained for >30 days
- Pharmacodynamic analyses:
  - **Rapid and sustained target engagement on both T cells and B cells**
  - **Reduction of cell surface BTLA expression**
  - **Duration of reduced BTLA expression persisted in a dose-dependent manner**



ANB032 in humans mirrored observation in animal models of inflammation supporting potential broad treatment of T and B-cell driven inflammatory diseases



## **ANB033 (Anti-CD122 antagonist mAb)**

Autoimmune and Inflammatory Diseases

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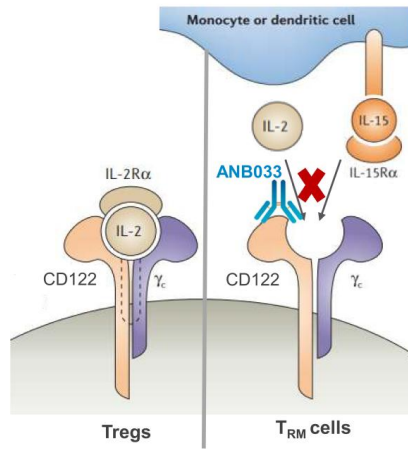
# ANB033: Anti-CD122 Antagonist mAb Targets Pathogenic Tissue Resident Memory T cells ( $T_{RM}$ )

IND filing targeted H1 2024



CD122 is a shared beta subunit of the receptors for IL-15 and IL-2

ANB033 MoA: Induce death of  $T_{RM}$  cells to achieve and maintain remission



- IL-15 mediates survival of  $T_{RM}$  cells
- Both IL-15 and IL-2 mediate:
  - Proliferation of T cells
  - Inflammatory cytokine secretion (IFN $\gamma$ ) during T cell activation
- High affinity antagonist antibody induces death in  $T_{RM}$  cells by preferentially inhibiting the lower affinity dimeric receptor complex
  - Spares Tregs which express higher affinity IL-2 trimeric receptor complex
- Targeted elimination of  $T_{RM}$  cells may potentially drive durable responses

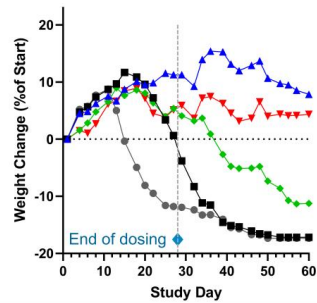
## ANB033: Durable Survival in GVHD Model

All mice treated at high-dose survived well beyond end of dosing

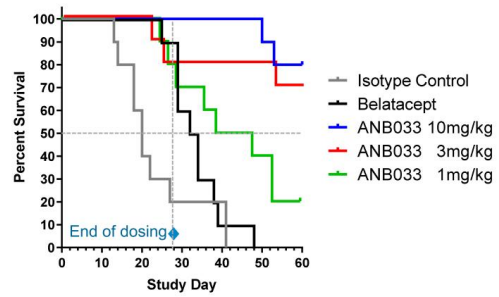


- GVHD (severe phenotype) model in human IL-15 transgenic mouse supports T cell and NK cell survival
- ANB033 preclinical data suggests targeted elimination of pathogenic  $T_{RM}$  drives more potent and durable response than belatacept
  - Belatacept (GVHD standard-of-care which only impedes T cell activation) shows minimal benefit over control

**Average Body Weights (carried)**



**Survival**



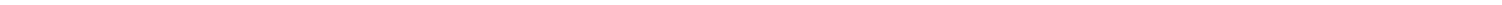
GVHD model is biologically relevant to CD122 antagonist MoA with translation to inflammatory diseases driven by pathogenic  $T_{RM}$  and Treg imbalance including rheumatology, dermatology, gastroenterology, and respiratory





## **Insidolimab (Anti-IL-36r antagonist mAb)**

Generalized Pustular Psoriasis (GPP)



## Generalized Pustular Psoriasis (GPP)

*Systemic inflammatory disease where IL-36 pathway plays key role in pathology*

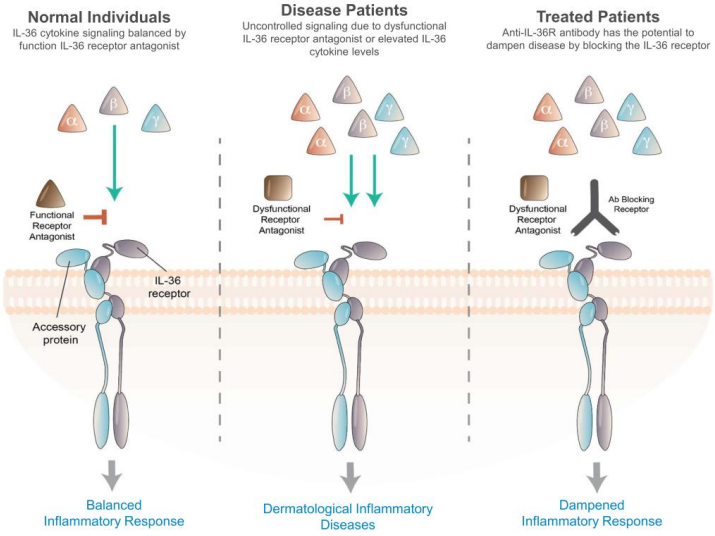


- GPP is a systemic, life-threatening inflammatory disease characterized by widespread pustules
  - Associated with unregulated IL-36 signaling
  - Patients have a high fever and elevated levels of serum CRP and inflammatory cytokines (e.g., IL-8)
  - Severe GPP patients can die from cardio-pulmonary failure, exhaustion, toxicity and infection
- GPP ICD-10 diagnostic code analysis by IQVIA assessed US prevalence during 2017-2019 timeframe
  - ~37,000 unique patients diagnosed at least once
  - ~15,000 unique patients diagnosed two or more times
- FDA has granted Orphan Drug Designation to insidolimab for the treatment of GPP
- Worldwide registry (RADIANCE) of GPP patients ongoing
  - Increase understanding of patient journey and support enrollment of Phase 3 trial



# Imsidolimab is an IL-36 Receptor Antagonist

Uncontrolled-IL36 signaling, as well as a genetic IL-36 association, mediates GPP



# GALLOP: Imsidolimab GPP Phase 2 Trial Top-Line Data

Presented at EADV Congress October 2021



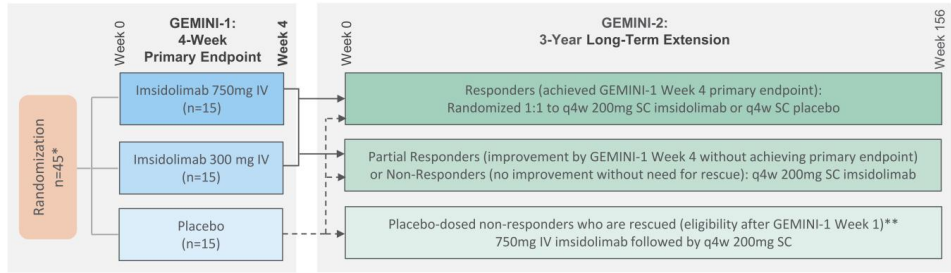
- Imsidolimab 750mg IV loading dose + 100mg SC q4w maintenance dose
- Rapid and sustained efficacy through week 16
  - 6 of 8 (75%) patients achieved primary endpoint of improvement in the clinical global impression scale (CGI)
  - Early reduction of erythema with skin pustules by week 1; sustained relative to baseline at week 16
  - GPP Physician Global Assessment (GPPGPA) demonstrated sustained efficacy through week 16
  - 2 patients dropped out of the study before Day 29 and deemed non-responders
- Imsidolimab generally well-tolerated
  - Most adverse events were mild to moderate and resolved without sequelae
  - Two subjects had serious adverse events and recovered without sequelae (sepsis due to *S. aureus* infection and SARS-CoV-2 injection)
- Genotypic testing indicated homozygous wild-type IL-36RN, CARD14 and AP1S3 alleles for all tested patients
  - IL-36R inhibition may be efficacious in GPP irrespective of genetic mutations

Endpoint	Baseline	Week 1 Relative to Baseline	Week 4 Relative to Baseline	Week 16 Relative to Baseline
CGI improvement (primary endpoint)	N/A	7 of 8 patients	6 of 8 patients	6 of 8 patients
mIDA-SI	9	-29%	-54%	-58%
Erythema with pustules (% body surface area)	24%	-60%	-94%	-98%
DLQI (MCID of -4)	16	-1	-6	-11



# GEMINI-1 & 2: Imsidolimab GPP Phase 3 Trials

GEMINI-1 top-line data anticipated Q4 2023



<b>Patient Population</b>	<ul style="list-style-type: none"> <li>Male and female subjects 18 to 80 years of age</li> <li>Clinically confirmed diagnosis of GPP as per ERASPEN definition</li> <li>Baseline Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score of at least moderate severity (3 and higher)</li> <li>Active flare with pustules and erythema accounting for at least 5% of body surface area at baseline</li> </ul>
<b>Key Endpoints</b>	<ul style="list-style-type: none"> <li>Primary: GPPPGA score of clear (0) or almost clear (1) at GEMINI-1 Week 4</li> <li>Key Secondary: Pustulation Rating Scale (PRS) of 0 or 1 at GEMINI-1 Week 1</li> <li>Other: Time to flare recurrence, proportion of subjects in remission, DLQI, safety</li> </ul>

ClinicalTrials.gov: NCT05352893, NCT05366855

\* 80% power calculated for GEMINI-1 using two-sided test alpha of 0.05 assuming ~40% effect size with 45 patient sample size

\*\*Starting at week 1 in GEMINI-1, placebo patients who have not improved or are worsening are eligible to be rescued with Imsidolimab



**GSK Immuno-Oncology  
Financial Collaboration**

JEMPERLI™ (dostarlimab, anti-PD-1 Antagonist)  
Cobolimab (GSK4069889, anti-TIM-3 Antagonist)  
GSK4074386 (TSR-033, anti-LAG-3 Antagonist)

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# Significant Residual Royalties from GSK Immuno-Oncology Financial Collaboration



## JEMPERLI (anti-PD-1 antagonist)

GSK anticipates ~\$1.2-2.4B peak annual sales for JEMPERLI in currently approved indications and anticipated 1L endometrial/ovarian approvals\*

- JEMPERLI 8% royalties on annual net sales <\$1B
- JEMPERLI \$15mm regulatory and \$90MM commercial milestone on annual net sales <\$1B

### Sagard: JEMPERLI Capped Non-Recourse Monetization

In 2H21, ANAB received \$250mm upfront in **exchange for only the above receivables until Sagard is paid back** one of the following capped returns: :

- \$312.5MM (125% of upfront) by end 2026 or
- \$337.5MM (135% of upfront) by end 2027 or
- \$412.5MM (165% of upfront) anytime after 2027

### Receivables Excluded from Sagard Monetization

- JEMPERLI 12-25% royalties on annual net sales ≥ \$1B
- JEMPERLI \$75mm commercial milestone on annual net sales ≥ \$1B

## Cobolimab (anti-TIM-3 antagonist)

### GSK4074386

(anti-LAG-3 antagonist)

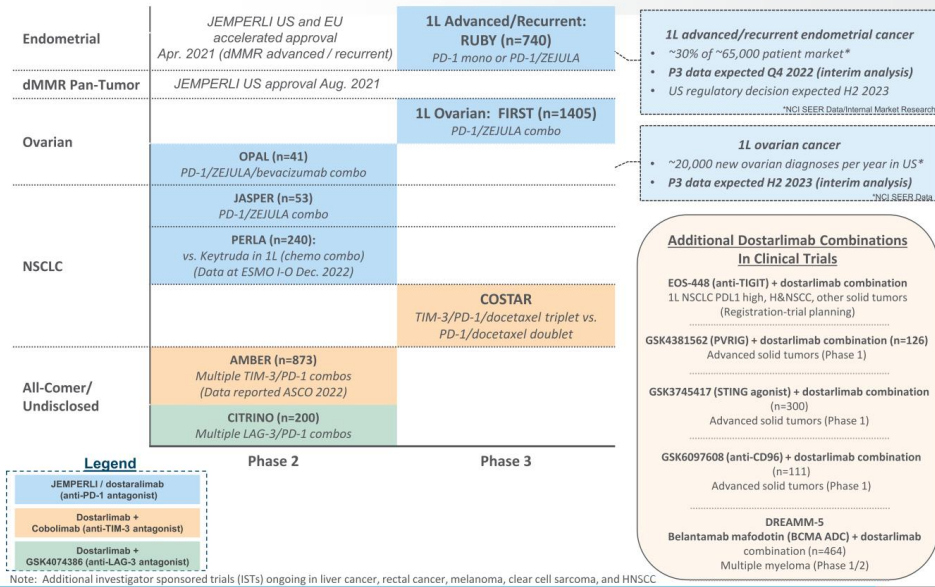
- Both programs being developed in combination with JEMPERLI
- 4-8% royalties on annual net sales on each program
- \$10mm clinical development, \$90mm regulatory and \$165mm commercial milestones on each program

\* In June 2021, GSK estimated potential peak annual global JEMPERLI sales on a non-risk adjusted basis of £1-£2 billion

Note: Sale of ZEJULA (niraparib) royalty interest in September 2022 to wholly-owned subsidiary of DRI Healthcare Trust for \$35mm upfront + \$10mm potential milestone upon FDA approval of ZEJULA for the treatment of endometrial cancer, for which the drug is currently in a fully-enrolled ongoing RUBY Phase 3 study of dostarlimab + niraparib, to the extent that such approval occurs on or before 12/31/25.

# GSK Immuno-Oncology Financial Collaboration: Clinical Trials

## JEMPERLI approved in the US and EU





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AnaptysBio 



