AnaptysBio Reports Positive Topline Data from Interim Analysis of GALLOP Phase 2 Clinical Trial of ANB019 Monotherapy in Moderate-to-Severe Generalized Pustular Psoriasis

- Interim analysis conducted with first two patients to complete 16-week (Day 113) ANB019 monotherapy study
- Both patients achieved the primary endpoint of disease score improvement at Day 29 and Day 113 without requiring rescue therapy
- Patients demonstrated rapid and sustained mJDA score improvement, with reduction of 58% at Day 8 and 63% at Day 113
- Complete clearance of skin pustules was achieved by Day 8 and through Day 113, while CRP decreased to nearly normal levels, in both patients

SAN DIEGO, Sept. 30, 2019 — AnaptysBio, Inc. (Nasdaq: ANAB), a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation, today announced positive topline data from an interim analysis of its Phase 2 clinical trial of ANB019 in moderate-to-severe generalized pustular psoriasis (GPP) patients, also known as the GALLOP trial. Enrollment is ongoing and AnaptysBio anticipates additional clinical data and a regulatory strategy update for the development of ANB019 in GPP during 2020. Moderate-to-severe GPP is a chronic, life-threatening, rare inflammatory disease with no approved therapies.

"Patients with GPP are urgently in need of safe and effective therapeutic options," said Hamza Suria, president and chief executive officer of AnaptysBio. "We are pleased with the benefit observed to date in this trial and look forward to data from additional patients as the GALLOP trial continues. In addition to GPP and palmo-plantar pustulosis, we believe excess IL-36 signaling may be involved in additional orphan dermatological indications, which represent potential future development opportunities for ANB019."

Interim Analysis

This interim analysis includes two patients that have completed Day 113 and comprises all of the data available from the ongoing Phase 2 study to date:

- Average baseline value for the modified Japanese Dermatology Association score (mJDA, Table 1) was 9, for body surface area covered by erythema and pustules was 27% and for serum C-reactive protein (CRP) was 34 mg/L.
- Both patients achieved the primary endpoint of the study, which is improvement in the clinical global impression scale (CGI, Table 2) at Day 29 and Day 113 with ANB019 monotherapy. Rescue therapy was not required by either patient.
- Rapid and sustained disease score improvement was observed in both patients (Table 3 and Figure 1). mJDA scores, which incorporate dermatological and systemic aspects of GPP, decreased by Day 8 and were maintained at 50% or greater reduction at almost all timepoints during the study. Skin pustules, which are the key dermatological sequelae of

GPP, were completely cleared in both patients by Day 8 and through Day 113. CRP, which measures systemic inflammation, decreased to nearly normal levels in both patients.

- Genotypic testing of these two patients indicated homozygous wild-type IL-36RN, CARD14 and AP1S3 alleles, which suggests that ANB019 may be broadly applicable to pustular disease patients without a requirement for genetic screening.
- Anti-drug antibodies were not detected in either patient.

ANB019 was generally well-tolerated and no serious or severe adverse events were reported in this interim analysis. Separately, one additional patient dropped out of the trial due to diagnosis with *Staphylococcal aureus* bacteremia on Day 3 post-ANB019 administration, which was a serious adverse event deemed to be possibly drug-related. Because this patient had a prior medical history of bacteremia, which is a common morbidity of GPP, the Company does not believe this event is likely due to ANB019 treatment. No data on this patient were collected post-ANB019 administration and therefore this patient was not included in the interim analysis.

Parameter	Timepoint	Reduction Relative to Baseline		
		Patient 1	Patient 2	Average
mJDA Score	Day 8	67%	50%	58%
	Day 15	50%	58%	54%
	Day 22	50%	67%	58%
	Day 29	33%	67%	50%
	Day 57	50%	67%	58%
	Day 85	67%	75%	71%
	Day 113	50%	75%	63%
Body surface area covered by erythema with pustules	Day 8	100%	100%	100%
	Day 15	100%	100%	100%
	Day 22	100%	100%	100%
	Day 29	100%	100%	100%
	Day 57	100%	100%	100%
	Day 85	100%	100%	100%
	Day 113	100%	100%	100%
CRP	Day 8	3%	90%	47%
	Day 15	11%	95%	53%
	Day 22	61%	96%	78%
	Day 29	64%	96%	80%
	Day 57	78%	92%	85%
	Day 85	59%	94%	77%
	Day 113	57%	93%	75%

Table 3. Reduction in mJDA score, body surface area covered by erythema with pustules and CRP following ANB019 administration for the two patients included in this interim analysis.

GALLOP Phase 2 Trial Design

This Phase 2 trial is enrolling up to 10 severe adult GPP patients at 7 sites in the United States and the United Kingdom. Key inclusion criteria include active ongoing GPP disease with a minimum mJDA score of 7 and at least 10% body surface area covered by pustules, while key exclusion criteria include concomitant dermatological conditions or infection. Each patient included in this interim analysis completed a washout period of at least 4 weeks prior to Day 1. Patients are dosed with a 750mg intravenous loading dose of ANB019 at Day 1, followed by monthly 100mg subcutaneous doses on Days 29, 57 and 85. Rescue therapy, including cyclosporine, methotrexate and retinoids, is permitted if any enrolled patient does not show improvement, in accordance with CGI relative to baseline, by Day 29. Patients are deemed to have achieved the primary endpoint if they demonstrate improvement in the CGI scale on Day 29 and Day 113 without any use of rescue therapy. Baseline clinical assessments are conducted for each patient on Day 1 prior to ANB019 dosing.

Based on the results of this interim analysis, AnaptysBio is curtailing the washout period required prior to enrollment.

About GPP
Moderate-to-severe GPP is a chronic, life-threatening, rare inflammatory disease with no currently approved therapies. Typically diagnosed after age 30, these patients can die from complications of bacteremia, sepsis, acute respiratory distress syndrome and cardiac failure. Most patients are treated with systemic anti-inflammatory agents, including high-dose cyclosporine, methotrexate and retinoids, which are often tapered or discontinued due to toxicity. Primary market research, including ICD-10 code claims, indicate that at least 3,000 moderate-to-severe GPP patients in the United States are regularly treated by dermatologists. GPP is known to be associated with excess signaling through the IL-36 receptor, which can be caused by genetic mutations and environmental factors.

About ANB019
ANB019 is an antibody that inhibits the function of the interleukin-36-receptor, or IL-36R, which AnaptysBio plans to initially develop as a potential first-in-class therapy for patients suffering from generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP. AnaptysBio has previously presented data from a Phase 1 clinical trial, which demonstrated favorable safety, pharmacokinetics and pharmacodynamic properties that supported advancement of ANB019 into Phase 2 studies. AnaptysBio is conducting its GALLOP trial, a Phase 2 study of ANB019 in GPP where additional clinical data and a regulatory strategy update is anticipated in 2020. The Company is also conducting its POPLAR trial, a Phase 2 study in PPP where top-line data is anticipated in the first half of 2020.

About AnaptysBio
AnaptysBio is a clinical-stage biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation. The Company's proprietary anti-inflammatory pipeline includes its anti-IL-33 antibody etokimab, previously referred to as ANB020, for the treatment of moderate-to-severe atopic dermatitis, eosinophilic asthma, and adult chronic rhinosinusitis with nasal polyps, or CRSwNP; its anti-IL-36R antibody ANB019 for the treatment of rare inflammatory diseases, including generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP; and its PD-1 agonist program, ANB030, and other novel anti-inflammatory checkpoint receptor modulator antibodies for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated. AnaptysBio's antibody pipeline has been developed using its proprietary somatic hypermutation, or SHM platform, which uses in vitro SHM for antibody discovery and is designed to replicate key features of the human immune system to overcome the limitations of competing antibody discovery technologies. AnaptysBio has also developed multiple therapeutic antibodies in an immuno-oncology partnership with TESARO, a GSK company, including an anti-PD-1 antagonist antibody (dostarlimab (TSR-042)) which is anticipated to achieve BLA filing in late 2019, an anti-TIM-3 antagonist antibody (TSR-022) and an anti-LAG-3 antagonist antibody (TSR-033), and an inflammation partnership with Celgene, including an anti-PD-1 checkpoint agonist antibody (CC-90006) currently in clinical development.

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 ANB019's Phase 2 clinical trials in GPP and PPP; timing of a regulatory strategy update for GPP; and statements by AnaptysBio's president and chief executive officer. 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.

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mJDA Index Components		Score			
		0	1	2	3
Dermatological components, % of body surface area covered by	Erythema with pustules	0%	>0%, <10%	≥10%, <50%	≥50%
	Erythema	0%	>0%, <25%	≥25%, <75%	≥75%
	Edema	0%	>0%, <10%	≥10%, <50%	≥50%
Systemic components	Fever (degrees C)	<37	≥37, <38.5	≥38.5	Not applicable
	White blood cell count (/microliter)	<10,000	≥10,000, <15,000	≥15,000	Not applicable
	CRP (mg/L)	<3	≥3, <70	≥70	Not applicable
	Serum albumin (g/L)	≥3.8	<3.8, ≥3.0	<3.0	Not applicable

Table 1. Patient mJDA scores are calculated by aggregating the above component scores at each timepoint. Moderate-to-severe patients range from a minimum of 7 to a maximum of 17 on the mJDA index. Adapted from Imafuku et al, J. Dermatology, 2016; 43:1011-1017, Table S1.

CGI Improvement Levels	Improvement Criteria		
	mJDA score change relative to baseline	and/or	Other parameters
Very much improved	Reduction by ≥3 points	or	Clear or almost clear signs of GPP
Much improved	Reduction by 1 or 2 points	or	Reduction in pustules by 30%, or clinically meaningful improvement of at least 2 other components of the mJDA
Minimally improved	No change	and	Reduction in pustules by 20%, or clinically meaningful improvement of at least 1 other components of the mJDA
No change	No change	and	Did not meet the criteria of "minimally improved"
Worsened	≥1 point increase		Not applicable

Table 2. CGI objectively determines disease improvement and need for rescue therapy. Rescue therapy was permitted only if a patient did not show improvement (minimally, much or very much improved) with ANB019 monotherapy by Day 29. Adapted from Imafuku et al, J. Dermatology, 2016; 43:1011-1017, Table S2.

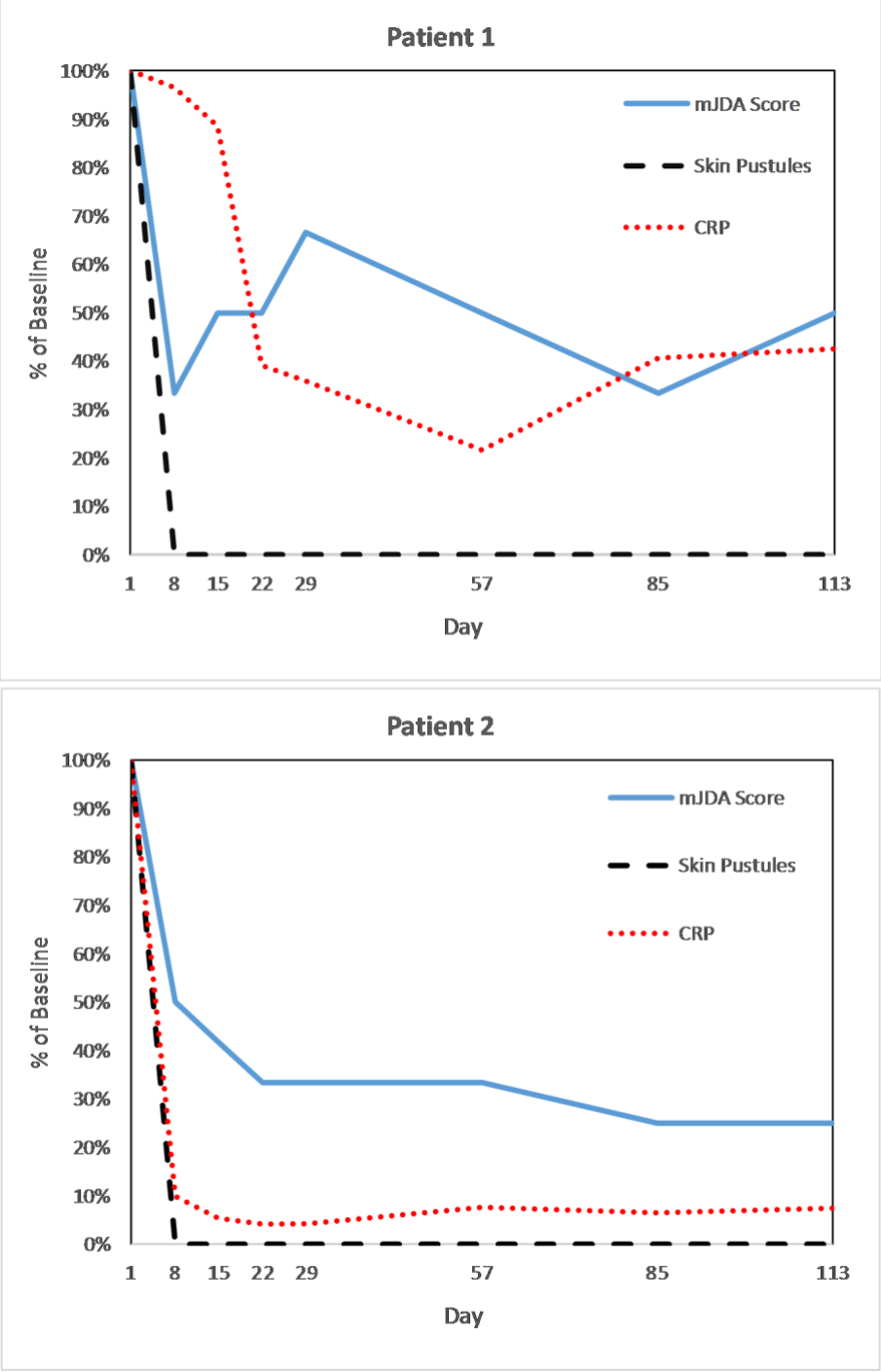

Figure 1. mJDA score, skin pustules and CRP as percentage of baseline for Patient 1 and 2.