

# Asana BioSciences, LLC

For Immediate Release

Asana BioSciences Initiates Phase 2b Study of ASN002 in Patients with Moderate-to-Severe Atopic Dermatitis (RADIANT)

Lawrenceville, NJ, July 19, 2018 – Asana BioSciences, a clinical stage biopharmaceutical company focused on discovery and development of novel targeted investigational medicines in Immunology/Inflammation and Oncology, today announced initiation of a Phase 2b study of ASN002, an oral JAK/SYK inhibitor, in patients with moderate-to-severe atopic dermatitis (AD). "I was impressed by the high efficacy of ASN002 in the first atopic dermatitis study. I am now very pleased to see that the Phase 2b is ongoing and enrolling fast," said Dr. Robert Bissonnette, the President of Innovaderm Research, Montreal, Canada, and a lead investigator for the ASN002 Phase 1b and Phase 2b RADIANT study.

In the recently concluded Phase 1b study in patients with moderate-to-severe atopic dermatitis, ASN002, dosed at 40 and 80 mg once daily, was well tolerated and showed clear evidence of clinical efficacy per EASI score and rapid symptom improvement, with significant reduction in patient-reported itch as early as day 2. These clinical improvements were associated with significant reductions in CD3+ T-cell and CD11c+ dendritic cell infiltration in skin, changes in AD-associated skin and serum biomarkers, and resolution of epidermal hyperplasia.

"We believe ASN002 is the first JAK inhibitor to report parallel improvements in clinical, histological and molecular parameters in AD skin lesions," said Dr. Sandeep Gupta, Founder and CEO of Asana BioSciences. "These compelling data indicate the potential of ASN002 as an important treatment option for patients with moderate-to-severe atopic dermatitis, as well as its potential applications for other dermatologic and auto-immune diseases."

About the ASN002 Phase 2b RADIANT Study (Relief from Atopic Dermatites with JAK and SYK INhibiTion)

The ASN002 Phase 2b RADIANT study is a randomized, double-blind, placebo-controlled study designed to evaluate efficacy, safety, tolerability, and pharmacokinetics of ASN002 dosed once daily for 12 weeks in patients with moderate-to-severe atopic dermatitis. The study is expected to enroll approximately 220 patients at study sites in the United States, Canada and Germany.

Key eligibi<mark>lity cr</mark>iteria for adult patients enrolled in this study include chronic atopic dermatitis for at least 6 months with an EASI score of 16 or greater, an IGA score of 3 or greater, and a body surface area involving at least 10 percent at baseline.

Eligible trial participants will be randomly assigned to receive 40, 60 or 80 mg ASN002 once daily or placebo. Following the end of the 12-week treatment period, eligible patients may be provided with the option to enter a planned extension study. The primary outcome measure of the study is the change in Eczema Area and Severity Index (EASI) score from baseline to week 12. Secondary endpoints include Investigator's Global Assessment (IGA), pruritus scores (NRS), Patient-Oriented Eczema Measure (POEM) and Dermatology Life Quality Index (DLQI).

Additional information can be found at www.clinicaltrials.gov using identifier NCT03531957.

#### **About Atopic Dermatitis**

Atopic dermatitis (AD) is a common inflammatory skin disease that affects children and adults, characterized by pruritus (itch), a chronically relapsing course, a distinctive distribution of eczematous skin lesions, and often a personal or family history of atopic diseases. Moderate and severe AD can cover much of the body surface area and has substantial effects on quality of life.

Although primarily affecting the skin, AD is increasingly being recognized as a systemic disease with atopic as well as non-atopic comorbidities, with important implications for management and treatment. The nonlesional skin of patients with moderate-to-severe AD shows extensive immune and barrier abnormalities, reflecting the systemic nature of the disease.

Recent insights into the immune pathogenesis of AD, including a greater understanding of the role of TH2 and TH22 cytokine pathways, have led to translational opportunities and enabled the development of small molecules and biologics that target key cytokines involved in inflammation. In addition, SYK has been suggested to play a role in skin immunity in AD by targeting B-cell signaling and keratinocyte function.

#### About Asana BioSciences, LLC

Asana BioSciences is a clinical stage biopharmaceutical company based near Princeton, NJ. Asana is focused on discovery and development of novel targeted investigational medicines in Inflammation / Immunology and Oncology. Multiple assets from Asana's portfolio are currently in clinical development including its lead asset ASN002.

Asana's second clinical lead molecule **ASN003** is a selective inhibitor of BRAF and PI3 Kinases. The RAS-RAF-MEK and PI3K pathways are frequently mutated in many cancers. Dual targeting of RAF and PI3K pathways has the potential to overcome and/or delay acquired resistance to selective RAF inhibitors and demonstrate improved efficacy against cancers driven by both pathways. Enrollment is ongoing in a Phase I study in patients with BRAF<sup>V600</sup> mutated metastatic melanoma, metastatic colorectal cancer, or advanced non-small cell lung cancer, and advanced solid tumors with documented PIK3CA mutation (**NCT02961283**).

**ASN007** is the third molecule in clinical development, which is a potent inhibitor of the extracellular-signal-regulated kinases, ERK1 and ERK2, key players in the RAS/RAF/MEK/ERK (MAPK) signaling pathway. ASN007 is being evaluated in a Phase I study in patients with advanced solid tumors, including BRAF and KRAS mutant cancers (**NCT03415126**).

**ASN004** is an Antibody-Drug-Conjugate (ADC) that targets the 5T4 oncofetal antigen, which is expressed in a wide range of malignant tumors, while very limited expression is found in normal tissues. ASN004 demonstrates robust and durable antitumor activity after single administration in multiple human tumor xenograft models. A First-in-Human Phase I trial is currently planned for initiation in 2019.

**ASN008** is a novel, topical Na<sup>+</sup>-channel blocker with high functional selectivity for itch and painsensing neurons. It is being developed for the treatment of chronic itch conditions and pain with rapid onset and long duration of action after a single application. The IND filing is currently planned for 2H 2018.

## www.asanabiosciences.com

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