

Asana BioSciences, LLC

For Immediate Release

Asana BioSciences Announces Achievement of Positive Results in the Clinical Proof of Concept Study in Atopic Dermatitis with ASN002, A Novel Oral JAK/SYK Inhibitor

Lawrenceville, N.J., January 4, 2018 – Asana BioSciences, a clinical stage biopharmaceutical company, today announced that ASN002, its oral once daily dual JAK/SYK inhibitor, has achieved clinical efficacy in a proof of concept study in patients with moderate-to-severe atopic dermatitis. In a double blind, placebo controlled, dose-ranging Phase 1b study conducted at multiple sites in the USA and Canada, ASN002 met the safety and efficacy endpoints after 4 weeks of treatment and was well tolerated.

“We are very excited about the results of our recently concluded clinical study with ASN002 in moderate-to-severe atopic dermatitis patients. ASN002 is the only oral compound in clinical development targeting JAK (including Tyk2) and SYK signaling, two clinically validated mechanisms,” said Sandeep Gupta, Ph.D., Founder, CEO and President of Asana BioSciences. “Dysregulation of Th2 and Th22 cytokine pathways is implicated in the pathogenesis of atopic dermatitis. The inhibition of JAK and SYK pathways diminishes cytokine production and signaling including those mediated by Th2 and Th22 cytokines. The clinical safety and efficacy data to date indicate that ASN002 has the potential to be an important treatment option in atopic dermatitis as well as other dermatological and auto-immune diseases,” said Dr. Gupta.

ASN002 showed robust clinical efficacy with nearly all patients obtaining a 50% improvement in disease severity (EASI50) at 40mg and 80mg once daily and substantial decreases in patient-reported itch measured by Numeric Rating Scale (NRS) after 4 weeks of treatment. More subjects treated with ASN002 achieved an improvement to 0-1 in their Investigator’s Global Assessment (IGA) relative to subjects who received placebo. Improvements with ASN002 were also observed in a reduction of body surface area (BSA) of skin involvement. ASN002 showed dose-dependent exposure in patients and caused reductions in several serum inflammation biomarkers including cytokines.

Dr. Emma Gutman-Yassky, the Sol and Clara Kest Professor of Dermatology, Vice Chair, Department of Dermatology, and Director of the Eczema Center and Laboratory for Inflammatory Skin Diseases at the Icahn School of Medicine at the Mount Sinai Medical Center in NY stated “We currently do not have safe oral treatments for treating our moderate-to-severe AD patients, and available immune suppressants harbor many side effects. It is exciting to have a novel oral therapeutic option such as ASN002 that can achieve rapid disease control in patients with moderate-to-severe AD and also seems to be well tolerated. Larger and longer studies are needed to show long-term disease control and safety over time, but this is very exciting news so far.”

In the current Phase 1b study, the safety and tolerability profile of ASN002 at all dose levels was excellent. The most common adverse event (AE) observed was transient, mild headache, mostly restricted to Day 1. There were no clinically significant laboratory changes including hematological parameters observed in this study.

The detailed efficacy and safety results of this study will be presented in scientific conferences in the near future. Asana will be initiating a Phase 2b study of ASN002 in moderate-to-severe atopic dermatitis patients in the early part of 2018. Clinical studies in other dermatological and autoimmune indications are under evaluation.

About Asana BioSciences, LLC

Asana BioSciences, is a research and development company based near Princeton, NJ, specializing in the discovery and development of new chemical and biological entities. Multiple assets from Asana's portfolio are currently in clinical development in a variety of therapeutic areas, including oncology, dermatology and autoimmune diseases. Asana is an independent member of the AE Companies, Bridgewater, NJ.

Asana's lead molecule **ASN002** is an investigational product, its efficacy and safety has not been fully established and is not approved by the FDA or other regulatory authorities. **ASN002** is also currently being evaluated in a Phase I/II clinical study in patients with non-Hodgkin lymphomas (NHL), peripheral T-cell lymphoma (PTCL), chronic lymphocytic leukemia (CLL) and myelofibrosis (MF), with early evidence of clinical activity and good tolerability (NCT02440685).

ASN003, a selective inhibitor of BRAF and PI3 Kinase, is currently in Phase I development in patients with advanced solid tumors (NCT02961283). The RAS-RAF-MEK and PI3K pathways are frequently mutated in melanoma and other cancers, such as colon and lung cancer. Dual targeting of RAF and PI3K pathways with ASN003 has the potential to overcome and/or delay acquired resistance to selective RAF inhibitors and improved efficacy against cancers driven by both pathways. To date, the drug is well tolerated in patients and shows pharmacodynamic activity. Enrollment is ongoing in patients with BRAF^{V600} mutated metastatic melanoma, metastatic colorectal cancer (CRC), or advanced non-small cell lung cancer (NSCLC), and advanced solid tumors with documented PIK3CA mutation.

ASN007 is a potent inhibitor of the extracellular-signal-regulated kinases, ERK1 and ERK2 (ERK1/2), key players in the RAS/RAF/MEK/ERK (MAPK) signaling pathway. This pathway is frequently hyper-activated in a wide range of cancers. ASN007 shows potent anti-proliferative activity in cancer lines that are selectively driven by the MAPK-pathway, including RAS mutant cell lines. Furthermore, ASN007 demonstrates strong inhibition of tumor growth in multiple BRAF and KRAS mutant patient-derived and cell line-derived xenograft models, including those that are resistant to BRAF and MEK inhibitors. ASN007 is being evaluated in a Phase 1 study in patients with advanced solid tumors, including BRAF and KRAS mutant cancers.

ASN004 is an Antibody Drug Conjugate (ADC) that targets the 5T4 oncofetal antigen that is expressed in a wide range of malignant tumors, while very limited expression is found in normal tissues. ASN004 demonstrates robust antitumor activity leading to complete tumor regressions in multiple human tumor xenograft models with no development of resistance to ASN004 treatment. The IND-enabling program for ASN004 has been completed and a First-in-Human Phase 1 trial is being planned in 2018.

ASN008 is a topical formulation of a novel Na⁺-channel blocker being developed for the treatment of chronic itch conditions and pain. In animal models of itch, ASN008 showed dose-dependent, rapid onset and long duration of action after a single application. The IND-enabling program has been initiated and a Phase 1 study is being planned.

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