Asana BioSciences, LLC
For Immediate Release

Asana BioSciences Announces Initiation of First-in-Human Clinical Study with ASN008, a Novel Topical Product for the Treatment of Pruritus Associated with Atopic Dermatitis

Lawrenceville, NJ, December 20, 2018 – Asana BioSciences, a clinical stage biopharmaceutical company, announced today that it has been granted permission by the U.S. Food and Drug Administration (FDA) to start human clinical trials with ASN008, a topical gel for the treatment of pruritus (itch) associated with atopic dermatitis.

“We are extremely pleased that FDA has allowed Asana to proceed with ASN008 in human trials. This represents our first topical drug to enter the clinic, and it expands our robust clinical development portfolio. This is our 6th successful IND application in a short span of about 4 years since the founding of Asana, which is a testament to the exceptional development capabilities and efficiency of the Asana team,” said Sandeep Gupta, Founder and CEO of Asana. “ASN008 is a novel, topical sodium channel blocker with high functional selectivity for itch and pain-sensing neurons that does not affect motor function. In preclinical models, ASN008 strongly inhibits the itch response, with a rapid onset and long duration of action after a single topical application. We have initiated the First-in-Human study in healthy volunteers and atopic dermatitis patients, which is the first of many indications we intend to study with ASN008.”

Zoe Diana Draelos, MD, a research and clinical board-certified dermatologist, Fellow of the American Academy of Dermatology, and President of Dermatology Consulting Services, PLLC stated “Topical itch control is a big unmet medical need. Itch is the most commonly experienced noxious sensory stimuli, which can be related to known cutaneous disease or unknown causes. It is a dominant symptom of atopic dermatitis and has a major impact on a patient's quality of life. Currently, there are no effective treatments for the control of itch, and the development of an effective pharmaceutical itch inhibitor will be a tremendous accomplishment. It will help physicians and patients in managing the underlying disease better, which is often exacerbated by itching”.

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 immunology/inflammation and oncology. Multiple assets from Asana’s portfolio besides ASN008 are in clinical development.

Asana’s lead asset for immunology/dermatology indications - ASN002, a novel dual inhibitor of JAK and SYK kinases - is in Phase 2b development in moderate-to-severe atopic dermatitis patients (NCT03654755). ASN002 has recently been granted Fast Track designation by the...
U.S. FDA and is the first oral drug to demonstrate improvement in atopic dermatitis lesional skin phenotype correlating with clinical efficacy. ASN002 is also being evaluated in patients with severe chronic hand eczema in a separate Phase 2b study (NCT03728504).

Asana also has several assets in clinical development for oncology. ASN003 is a selective inhibitor of BRAF and PI3 kinases. Dual targeting of RAF and PI3K pathways has the potential to overcome and/or delay acquired resistance to selective RAF inhibitors. A Phase I study in patients with BRAFV600 mutated metastatic melanoma, metastatic colorectal and advanced non-small cell lung cancer is ongoing (NCT02961283).

ASN007, also in Phase 1 clinical development, is a potent inhibitor of the extracellular-signal-regulated kinases ERK1 and ERK2, which are key players in the RAS/RAF/MEK/ERK (MAPK) signaling pathway. ASN007 is being evaluated 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 but has very limited expression 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.

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