Asana BioSciences, LLC

For Immediate Release

Asana BioSciences Announces Positive Topline Results from Phase 2b Study of Oral JAK/SYK Inhibitor Gusacitinib (ASN002) in Patients with Chronic Hand Eczema: Rapid and Significant Improvement Demonstrated

Lawrenceville, NJ, June 2, 2020 – Asana BioSciences announced today positive topline results from a Phase 2b study evaluating the efficacy and safety of its investigational oral Janus kinase family (JAK) and spleen tyrosine kinase (SYK) inhibitor gusacitinib (ASN002) in 97 adult patients with moderate-to-severe chronic hand eczema (CHE). The study was a randomized, double-blind, placebo-controlled, parallel-group study evaluating oral gusacitinib (40 mg or 80 mg once daily) for up to 32 weeks, with the primary endpoint of mean modified total lesion severity score (mTLSS) at week 16 (NCT03728504).

The topline results show that gusacitinib achieved a dose-dependent, clinically meaningful, and statistically significant improvement relative to placebo in both the primary and key secondary endpoints of efficacy. Gusacitinib 80 mg resulted in an overall decrease of 69% ($p<0.005$) in mTLSS from baseline, compared to a 49% decrease for 40 mg and 33% decrease for placebo. Both 40 and 80 mg doses resulted in 50% and 66% improvement, respectively, in the mTLSS pruritus sub-score at week 16. Topline results also show significant improvement in key secondary measures such as Physician's Global Assessment (PGA) with a 5-fold increase in subjects achieving clear or almost clear over placebo at 80 mg dose. Rapid and clinically relevant reductions in mTLSS ($p<0.005$), PGA ($p<0.05$) and pruritus were observed as early as 4 weeks and sustained for the duration of the study.

Safety results show that both doses of gusacitinib were well-tolerated. The most common treatment-emergent adverse events observed were upper respiratory tract infection, headache, nausea, and nasopharyngitis. No pulmonary embolism was reported in the gusacitinib groups. No opportunistic infections, malignancies, major adverse cardiovascular events (MACE), or deaths were reported in the study.

"Chronic hand eczema (CHE) is a debilitating condition that affects approximately 10% of the U.S. population and millions of people worldwide. Patients with CHE suffer greatly from this disease, which limits their ability to work and perform activities of daily living. Currently there are no approved treatments in the U.S., and therapies used for this condition are not very effective," said Emma Guttman-Yassky, M.D., Ph.D., Sol and Clara Kest Professor of Dermatology, Vice Chair, Department of Dermatology, Director of the Center for Excellence in Eczema and Director of the Laboratory of Inflammatory Skin Diseases in the Department of Dermatology at Icahn School of Medicine at Mount Sinai in New York. Dr. Guttman-Yassky added that "Disease drivers of CHE are multifactorial with genetics, atopy, contact allergens and irritating substances playing a role in 'triggering' the disease. JAK/SYK inhibitors, such as

gusacitinib, can impact several pathways involved in inflammation of CHE and other dermatologic and inflammatory diseases, thus holding promise as potential therapeutics."

"These topline findings are very impressive and provide evidence that gusacitinib, if approved, could be an effective new oral once-daily treatment option for patients suffering from chronic hand eczema who are unable to achieve adequate control with topical corticosteroids and other unapproved treatments. Gusacitinib showed a quick onset of efficacy, as significant improvements in both primary and key secondary endpoints were observed during the first 4 weeks of treatment, and these were sustained over the study period," said Howard Sofen, MD, Medical Director of Dermatology Research Associates, Associate Clinical Professor of Medicine/Dermatology, Geffen School of Medicine, UCLA, Consultant Dermatologist at LA County/Olive View Medical Center in Los Angeles, and one of the lead investigators of the Phase 2b study.

"We are excited by the results of this Phase 2b clinical study," said Sandeep Gupta, PhD, Founder and CEO of Asana BioSciences. "Gusacitinib represents a First-to-Market opportunity for CHE as currently there are no approved treatments for this often-debilitating disease in the U.S. and many other major markets. We look forward to advancing gusacitinib to Phase 3 development and making it available for patients suffering from moderate-to-severe CHE."

Gusacitinib, a potential best-in-class JAK/SYK inhibitor, has been studied in over 400 subjects to date including an earlier Phase 2b study (RADIANT) in 244 adult patients with moderate-to-severe atopic dermatitis and has shown good safety and tolerability. The RADIANT trial was a randomized, double-blind, placebo-controlled, parallel-group study evaluating three doses of gusacitinib (40, 60, and 80 mg once daily) over 12 weeks (NCT03654755). Gusacitinib showed a rapid and statistically significant reduction in pruritus as well as a statistically significant reduction in EASI score from baseline in moderate-to-severe AD patients.

About Gusacitinib (ASN002)

Gusacitinib (ASN002) is a potent inhibitor of the Janus kinase (JAK) family (JAK1, JAK2, JAK3 and TYK2) and spleen tyrosine kinase (SYK). Autoimmune, inflammatory and immunological-based diseases, including atopic dermatitis, have complex pathogeneses that involve interactions between multiple cytokines and immune cells. JAK kinases play a significant role in these inflammatory conditions. The JAK kinases family (JAK1, JAK2, JAK3 and TYK2) is involved in signaling pathways of the Th2, Th22, Th1 and Th17 cytokines involved in AD pathogenesis. Hence, JAK kinases play a significant role in inflammatory conditions, particularly those driven by cytokines. SYK is a vital mediator of immunoreceptor signaling in macrophages, neutrophils, mast cells, and B cells. SYK mediated signaling leads to increased release of inflammatory cytokines, lipid mediators, and various proteases. Activated B cells and macrophages also act as antigen presenting cells and potent activators of T cells in inflammatory conditions. SYK also plays a critical role in IL-17R signaling in keratinocytes and in keratinocyte proliferation and terminal differentiation.

In order to effectively treat these complex diseases, gusacitinib simultaneously targets multiple disease-relevant signaling pathways to allow for greater control over those pathways that drive disease pathogenesis. SYK-JAK inhibition with gusacitinib modulates Th2, Th22, Th1 and Th17 cytokines, thereby targeting both the immune cells and epithelial cells responsible for the disease pathogenesis of CHE. This multi-pathway approach holds promise for treating a wide range of dermatological diseases such as CHE, atopic dermatitis, alopecia, psoriasis, hidradenitis suppurative, and inflammatory conditions including systemic lupus erythematosus, ankylosing spondylitis, psoriatic arthritis, and rheumatoid arthritis.

About Asana BioSciences, LLC

Asana BioSciences is a clinical stage biopharmaceutical company based in Lawrenceville, NJ. Asana is focused on discovery and development of novel targeted investigational medicines in immunology/inflammation and oncology.

Asana's second immunology/dermatology asset ASN008 is a novel, topical Na+-channel blocker with high functional selectivity for itch and pain sensing neurons without affecting motor nerves. In a Phase 1b study in atopic dermatitis patients, topical application of ASN008 showed rapid onset of pruritus relief after a single application, which lasted between 8-12 hours, and no tachyphylaxis to this response was observed after 2 weeks of daily application (NCT03798561). ASN008 also has potential for the treatment of pain, urologic and other chronic conditions.

Asana also has several oncology assets. Asana's lead oncology asset, ASN007, 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 has completed Phase 1 dose-finding showing encouraging efficacy and is in clinical development in patients with advanced solid tumors, including RAF- and RAS-mutant cancers (NCT03415126).

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. ASN003 is in Phase 1 development in patients with BRAFV600 mutated metastatic melanoma, metastatic colorectal and advanced non-small cell lung cancer (NCT02961283).

ASN004 is an antibody drug conjugate 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 1 trial is being planned.

Asana is also developing ASN009, a highly selective antagonist of the purinergic P2X3 ion channel that is activated by extracellular ATP and involved in various pain, urological and respiratory disease conditions. Preclinical proof-of-concept has been demonstrated with ASN009 in a cough model. ASN009 is currently in preclinical development.

www.asanabiosciences.com

Contact:

David Zammit
Asana BioSciences
997 Lenox Drive, Suite 220
Princeton Pike Corporate Center
Lawrenceville, NJ 08648
Ph: 908-698-0486
David.Zammit@asanabio.com