

News Release

April 8, 2021

Mitsubishi Tanabe and Mineralys entered into the exclusive License Agreement for a cardiovascular agent "MT-4129" and FDA Accepts IND Application

Mitsubishi Tanabe Pharma Corporation (MTPC, Head Office: Chuo-ku, Osaka; President & Representative Director, CEO: Hiroaki Ueno) announced today that MTPC licensed out an aldosterone synthase inhibitor "MT-4129" to Mineralys Therapeutics, Inc (Mineralys, Head Office: Pennsylvania, US; CEO: Jon Congleton and the U.S. Food and Drug Administration (FDA) has accepted Mineralys' Investigational New Drug Application (IND) for an investigational compound MT-4129 for the treatment of hypertension.

In the Phase 1 clinical trial of MT-4129 (Mineralys code: MLS-101) conducted by MTPC, the agent showed a safe and tolerable profile and selectively reduced the aldosterone level in healthy volunteers. Aldosterone is considered one of underlying causes of hypertension and recognized as an ideal target for therapeutic intervention in hypertension patients.

Mineralys, a private, clinical-stage biopharmaceutical company founded by Catalys Pacific, a venture capital firm. Mineralys will soon start enrolling patients to conduct the Phase 2 clinical trial of MT-4129.

At MTPC, we are aiming to maximize value of our original products line through global development and commercialization, not only in-house development but also by out-licensing to appropriate partners. In such efforts, MTPC continues striving to be able to offer new treatment options to patients around the world faster.

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■ About Mineralys Therapeutics Inc.

Headquartered in Philadelphia, PA, Mineralys Therapeutics, Inc. is a private, clinical-stage biopharmaceutical company committed to developing best-in-class, novel therapies for the treatment of hypertension. The Company is driven to bring a targeted approach to the management of hypertension via the development of MLS-101 (MT-4129). MLS-101, licensed from Mitsubishi Tanabe Pharma Corporation, is a highly selective and potent aldosterone synthase inhibitor that is being investigated for the treatment of hypertension.

■ About MT-4129 (MLS-101)

MT-4129 (MLS-101) is a highly selective and potent aldosterone synthase inhibitor, originated by Mitsubishi Tanabe Pharma Corporation., that is being investigated for the treatment of hypertension. It selectively inhibits the CYP11B2 pathway responsible for synthesis of aldosterone and has no untoward effects of blocking the mineralocorticoid receptors, thereby significantly reducing plasma aldosterone levels without affecting other hormones like cortisol.

MLS-101 has been studied in healthy volunteers in a Phase 1 program that validated the aldosterone reducing effects of MLS-101 and demonstrated a safe and tolerable clinical profile.