

# Polaryx Therapeutics Provides Corporate Update

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- Focused on launching STARLIGHT Phase 3 clinical trial for lead drug candidate, PLX-200, in treatment of CLN3; IND-approved CLN2 trial also in prep

- Completed development of novel, patient-friendly oral solution and continuing research and development of buccal formulation

- Exploring partnership opportunities to accelerate clinical development



[Polaryx Therapeutics](#) ("Polaryx"), a clinical biopharmaceutical company developing effective and patient-friendly therapies for rare, inherited lysosomal storage disorders ("LSD"), today provides an update on clinical and corporate development plans.

## PROGRAM OVERVIEW

Polaryx's pipeline of therapies - PLX-100, PLX-200 and PLX-300 - focus on a range of rare inherited lysosomal storage disorders such as Batten disease (Neuronal Ceroid Lipofuscinosis), Krabbe disease, Tay Sachs/Sandhoff disease, and Niemann-Pick Type A/B disease. As many of these diseases currently have no available treatment options, development of Polaryx's potentially disease-modifying therapies has a great unmet medical need.

## CLINICAL UPDATE

In the near-term, Polaryx continues to focus on PLX-200, its lead drug candidate, and on

launching STARLIGHT, a Phase 3 pivotal clinical trial evaluating PLX-200 in 39 participants with mild-to-moderate CLN3 (Juvenile NCL). CLN3 has no current treatment and is marked by lysosomal dysfunction resulting in substantial co-morbidities and eventually premature death.

Polaryx additionally continues to prepare PLX-200 for a Phase 3 pivotal trial of 26 mild-to-moderate CLN2 (Late Infantile NCL) children. CLN2 has one treatment available that is delivered at high cost in a hospital environment through a distinctly patient-unfriendly intracerebroventricular administration.

## DRUG PRODUCT UPDATE

Consistent with Polaryx's commitment to patient-friendly administration compared to the current standard of care, Polaryx has completed the development of a high-compliance oral solution that increases dosing control, palatability, and bioavailability. Further research and development of buccal and oral solution and suspension formulations with enhanced bioavailability will continue.

"Polaryx is intensely focused on delivering patient-friendly therapies for lysosomal storage disorders. Our proprietary oral liquid dosage forms are central to our ability to deliver accurate and safe dosing of our therapies – especially critical as many LSDs affect pediatric patients," commented Hahn-Jun Lee, M.Sc., Ph.D., Polaryx's President and Chief Executive Officer.

## PARTNERSHIP UPDATE

With PLX-200 on the cusp of initiating Phase 3 pivotal trials in two indications, Polaryx is moving to identify partners to advance the development timeline and move therapies closer to commercialization. In support of that goal, MTS Health Partners has been retained as a financial advisor to assist in the search for a partner.

"We are very pleased with Polaryx's clinical development to this point with two indications already approved for pivotal trials. Currently, we are also exploring partnering opportunities which will catalyze accelerated clinical development and move us closer to delivering our therapies to patients in need," said Alex Yang, JD, LLM, Executive Chair of the Board of Polaryx.

## ABOUT POLARYX THERAPEUTICS, INC.

Polaryx Therapeutics, Inc. is a multi-asset, late-stage clinical biopharmaceutical company developing patient-friendly small molecule therapeutics for rare, inherited lysosomal storage disorders such as Neuronal Ceroid Lipofuscinosis, Tay Sachs disease, Krabbe disease and Niemann-Pick disease Type A/B. Polaryx's drug candidates exhibit multiple mechanisms of

action to enhance cellular clearance pathways to eliminate cellular waste and additionally support neuronal survival.

Polaryx's largest shareholder is [Mstone Partners](#), an entrepreneurial biotech incubator in the form of a holding company which owns and manages a portfolio of drug development companies. Mstone focuses on rare, pediatric and repurposed drugs, neurodegenerative disorders and innovative technologies for targeted indications. Since 2016 inception, Mstone has invested in two US and one HK company, which are now in advanced clinical-stages with the US FDA. Mstone has also established a number of portfolio companies under the Curestone Platform, which manages a portfolio of drug development companies in a centralized, hub-and-spoke model.

For more information, please visit <https://www.polaryx.com/index.html>

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