C-Path to Lead Novel Pre-Consortium Framework for Optimizing the Rare and Orphan Medical Product Lifecycle

TUCSON, Ariz., April 28, 2022 — Critical Path Institute (C-Path), in collaboration with one of the industry's prominent rare and orphan (R&O) thought leaders, Maryna Kolochavina, Pharm.D., Ph.D., today announced the launch of a unique pre-consortium collaboration, bringing together industry leaders and stakeholders to accelerate and standardize key constructs for the efficient development, approval and access to R&O medical products.

This pre-consortium collaboration named '5-Voices,' will include representatives from the R&O disease stakeholder community, across nearly 200 potential member organizations. Its aim is to collaboratively develop an integrated framework which will set an optimized standard for accelerating the development and delivery of new R&O medical products to more patients.

The 5-Voices pre-consortium will have representation from five stakeholder groups to share their perspectives: 1) patient community, 2) sponsors, 3) funders, 4) regulators and 5) payers. The group will form an integrated strategy and operations for the rare and orphan medical product lifecycle and will focus on areas/workflows of unmet need and high rate of uncertainty, for which the envisioned consortium can provide tangible solutions and recommendations.

"Rare and orphan diseases are an area of unmet need for medical product development," said Kristen Swingle, M.S., C-Path Interim President and COO. "The 5-Voices pre-consortium effort will help determine the feasibility of a consortium that can contribute to significantly decrease the uncertainty in medical product development, approval and use through the collaboration of key stakeholders."

The R&O medical product lifecycle is moving from siloed functional activities towards a more integrated approach. The envisioned collaboration aims to contribute to this integration towards optimized processes for development, reimbursement and access. 5-Voices will put the patient experience at the center of the R&O medical product lifecycle and focus on common goals for efficient medical product development. "This pre-consortium effort aims to make the alignment of these 5-Voices achievable," said Swingle.

"We are all in agreement that it is truly important to listen to our patients and it is vital to make progress along the pathway towards additional, better and more accessible treatments for rare disease patients," said Kolochavina. There has been tremendous progress in the 40 years since the Orphan Drug Act was introduced. The added value of 5-Voices is that it brings the key constituents into a prospective collaboration, with rare disease patients and their families at the center."

The 5-Voices team looks forward to collaborating with the R&O community. To learn more and become engaged, please email info@c-path.org.

About C-Path

Critical Path Institute (C-Path) is an independent, nonprofit organization established in 2005 as a public and private partnership. C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established numerous global consortia that currently include more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and hundreds of pharmaceutical and biotech companies. C-Path U.S. is headquartered in Tucson, Arizona, C-Path in Europe is headquartered in Amsterdam, Netherlands and C-Path Ltd. operates from Dublin, Ireland with additional staff in multiple other locations. For more information, visit c-path.org.

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About Dr. Maryna Kolochavina

Dr. Maryna Kolochavina is one of the leading experts in R&O asset development and product commercialization. Throughout her career, Dr. Kolochavina has served as an Executive Leader, Trusted Advisor and Patient Advocate. She has dedicated her professional career to improving care for patients with R&O diseases. She has 17 years of experience in lifecycle medical product management for 220+ R&O medicinal products and advanced therapies in 44 therapeutic classes with 440+ orphan drug designations, resulting in approximately $4.5 bn in capital committed to alliances with biotechnology and pharmaceutical partners of all sizes.

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