

Civica Selects Profil as Clinical Trial Partner for Affordable Insulin Initiative

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LEHI, UTAH, June 2, 2022 – Civica, Inc. (Civica, Civica Rx) today announced the selection of Profil, Neuss, Germany, as its clinical trial partner to support the development of its affordable insulins. As previously [announced](#), Civica plans to produce three insulin biosimilars – glargine, lispro and aspart – each of which will be available both in vials and prefilled pens, and sell the insulins at significantly lower prices than insulins currently on the market. Human clinical trials are an important final step to demonstrate biosimilarity to branded insulins already in the marketplace.

Profil has conducted over 30 biosimilar insulin trials and is the leading clinical research organization for studies related to diabetes. Its experienced team includes physicians with decades of research experience in every aspect of diabetes management, including prediabetes, drug development, clinical care, insulin pharmacology and diabetes technology.

“The need for affordable insulin is urgent, especially for uninsured and underinsured populations,” said Ned McCoy, President and Chief Executive Officer of Civica Rx. “With its extensive experience and quality track record, Profil is the ideal clinical trial partner for Civica. We look forward to working with Profil to achieve our mission of providing insulins at one low, transparent price for all.”

“As experts in diabetes research and management, we acutely understand the vital, timely need for affordable insulin options,” said Dr. Tim Heise, Lead Scientist and Co-Founder of Profil. “We are thrilled to be partnering with Civica on this important initiative and look forward to bringing our extensive knowledge and experience in diabetes to help Civica provide more affordable insulins to people with diabetes, including those who often can’t afford this life-saving drug.”

Civica plans to set a maximum recommended price to the consumer of no more than \$30 per vial and no more than \$55 for a box of five pen cartridges, a significant discount to prices charged to uninsured individuals today.¹ It is collaborating on this effort with partners that represent nearly every corner of the diabetes ecosystem, including the diabetes community, health systems, payers and philanthropies. Contingent on FDA approval, Civica anticipates that its insulins will be available for purchase beginning in 2024.

About Civica and Civica’s Affordable Insulin Initiative

More information on Civica and its affordable insulin initiative, including commentary from partners and a fact sheet, can be found at <https://civicainsulin.org>.

About Profil

Profil is the leading clinical research organization for studies related to diabetes and obesity. Profil conducts pharmacodynamics, pharmacokinetics, biosimilar, safety and tolerability studies, as well as bridging studies and more. The Company has been involved in the development of an artificial pancreas

¹ Based on a publicly available current average list price of glargine (Lantus), lispro (Humalog) and aspart (Novolog) on <https://www.goodrx.com/> on February 28, 2022.



as part of the AP@home project and have been involved in the development of all classes of antidiabetic drugs. More information on Profil can be found at <https://www.profil.com>.

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