Press Release
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Prostatype Genomics submits Medicare reimbursement application in the US market for its gene test Prostatype®

Prostatype Genomics AB announces that its wholly owned subsidiary Prostatype Genomics Inc. has submitted its application for the Company's gene test Prostatype® to be approved for reimbursement by the Medicare healthcare system in the United States in line with the previously announced timeline. The Company continues to have Medicare approval in Q4 2024 as a business goal. The application is submitted within the MolDX program for molecular diagnostic tests. The US market is the world's largest single market for prognostic gene tests for diagnosed prostate cancer, with annual sales corresponding to approx. 2 billion SEK.

As there are already a few similar tests in the United States with the type of Medicare approval that the Company is now applying to obtain for Prostatype®, the implementation process following a positive decision is expected to go significantly faster than would otherwise have been the case. Currently, the Medicare reimbursement level for the product category is approx. 3,700 USD per test, and Medicare is the single largest and most important healthcare insurance provider in the United States.

“We are proud to take this important step towards establishing Prostatype® as the next-generation prognostic gene test for diagnosed prostate cancer in the US market. We are seeing great interest from American urologists who understand the significant value that the product can bring to both the patient and the healthcare provider. The Company's major business goal for 2024 has always been to obtain Medicare approval, and it is gratifying that we continue to follow our ambitious timeline to make this possible,” says Steven Gaal, President of Prostatype Genomics Inc.

“It has been a considerable effort for the whole company to reach this point, and we are pleased to note that our project plan and timeline for the US market holds up, and that yet another milestone has been achieved according to plan. Our whole team, both in Sweden and the United States, has done its outmost to enable an efficient processing of our application, and we are now looking forward to receiving the announcement from Medicare sometime in the next few months,” says Prostatype Genomics' CEO Fredrik Rickman.

Prostatype® is already commercially available in the US market, however without being included in Medicare's reimbursement system. The Company is, among other things, working with Professor E. David Crawford, MD, an internationally recognized expert in prostate cancer based at the University of California San Diego, to ensure that Prostatype® can be easily included into the workflow of American urologists when the Company initiates the commercial launch. Upon Medicare approval, the Company plans to initiate a focused commercial launch. The focus will be on the states and groups of urologists deemed to be the most appropriate by the Company, considering a number of identified criteria such as, among others, Medicare coverage and demographic profile. The Company will present the full business plan for the US market during the autumn.

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About Prostatype Genomics AB
Prostatype® is a genomic test that is available to patients and treating urologists as a complementary decision basis for the question of treatment or no-treatment of prostate cancer. The test was developed by a leading research group at Karolinska Institute and is provided by Prostatype Genomics AB.