NEWS RELEASE

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Aggredyne receives FDA clearance for ADP platelet aggregation testing cartridge

HOUSTON, TX, April 8, 2019 – Platelet testing and research company Aggredyne, Inc. has received U.S. Food and Drug Administration (FDA) clearance for its unique AggreGuide A-100® ADP Assay testing cartridge, a cost-effective in vitro diagnostic device used to measure the effect of various antiplatelet medications that target the platelet P2Y12 receptor.

The latest FDA clearance allows the company to market throughout the U.S. and further expands the menu of additional tests that can be used with the A-100® instrument. The companion A-100 AA assay cartridge, used to determine the effect of aspirin on platelet activity, and the A-100® instrument received FDA clearance in 2013.

The A-100 ADP cartridge was evaluated for clearance in several clinical sites in the U.S., using FDA-approved combinations of dual anti-platelet therapies (medications such as Plavix®, Brilinta® and Effient®). The ADP cartridge is unique in that it simulates whole blood flow in motion within its microfluidic reaction chamber, similar to that of flow within the human body. The companion A-100®

instrument uses laser light scattering to quickly quantify platelet aggregates in the sample. The individual test(s) require only a few drops of whole blood.

"Receiving FDA clearance for our A-100 ADP Assay cartridge is a significant milestone as we can now offer a full portfolio of innovative platelet testing technologies for hospitals, diagnostic labs or any duly-certified entity in the U.S.," said Aggredyne CEO and President Robert C. Hux. "Notably, the A-100 ADP Assay is the first assay that has been FDA-cleared for measuring the effect of the newer anti-platelet inhibitors Brilinta® and Effient®. We are now working toward obtaining the necessary regulatory classification to allow placement of our platelet testing devices directly in physician offices."

About Aggredyne, Inc.

Based in Houston, Texas, Aggredyne, Inc. (aggredyne.com) is a privately-held, investor- owned medical device manufacturing and research company, incorporated in 2012. The company, which holds ISO 13485 medical device quality certification, is focused primarily on manufacturing its A-100 AggreGuide® instrument and associated assays for testing platelet aggregation in the individual patients. The company's patented products are CE marked and available in various international territories. The company is also developing additional assays to be used with its instrument(s) in the anti-platelet therapy field as well as in related disease states.

For specific information on what products are available for sale in a particular country, please contact a local Aggredyne Inc. distributor or contact us at info@aggredyne.com