TricValve® Transcatheter Bicaval Valves System granted Designation as Breakthrough Device by the U.S. Food and Drug Administration (FDA)

Vienna, December 22nd 2020

TricValve® made in Europe

P+F Products + Features GmbH has been granted designation as a Breakthrough Device for the company´s lead product, the TricValve® Transcatheter Bicval Valves System by the U.S. Food & Drug Administration on December 15th 2020. The TricValve® is a system of two self-expanding biological valves for the treatment of patients with hemodynamically relevant tricuspid insufficiency and caval reflux. "*The TricValve® system represents a new technology offering a potentially simple, relatively low-risk yet effective treatment for patients with symptomatic severe* tricuspid regurgitation *(TR) and heart failure, many of whom harbor anatomy unfavorable for edge-to-edge repair or direct annuloplasty. It allows for all future options as patients stabilize and improve. We look forward to clinical trials in the US to further evaluate its safety and efficacy", said* Prof. Samir Kapadia, Chairman Dept. of Cardiovascular Medicine and Prof. Rishi Puri, Interventional Cardiology, Cleveland Clinic.

About TricValve®

The dedicated TricValve® bioprostheses are implanted percutaneously into the inferior and superior vena cava without disturbing the native tricuspid valve.
They are especially intended for use for patients at extreme risk or who are inoperable for open surgical therapy. The valves come fully pre-mounted thus facilitating the use of this innovative device in daily clinical practice.
"It is a huge milestone to receive the breakthrough device status for the TricValve®. This could be a big change in the treatment of patients with severe TR made in Europe", said CEO of P+F, Dr. Katharina Kiss.
The TricValve® is currently undergoing CE certification process. CE mark is expected in Q1 2021.

About P+F

With more than 25 years of experience in the medical field, the leadership team of P+F has built a complete infrastructure for research, development, manufacture, and distribution. P+F is developing a full pipeline of transcatheter heart valves and grafts, as well as the Aortasave – a Transcatheter Endobentall solution for Aortic Dissection.

Headquartered in Vienna, Austria, P+F has production sites in Europe, Asia and Brazil. P+F has recently entered into Joint Ventures with OrbusNeich® for the APAC region and with Relisys Medical Devices Ltd. for the Indian subcontinent and neighbouring countries.

For more information, visit https://productsandfeatures.com.

Press contact:
P+F Products + Features GmbH
Isabelle Glöckner
Argelsrieder Feld 1a | 82234 Wessling / Germany
office: +49 8153 99 70 930
e-mail: isabelle.gloeckner@productsandfeatures.com