FDA Grants Orphan Drug Designation to Zytoprotec’s Novel Dialysis Fluid

- Dialysis solution to improve outcomes of peritoneal dialysis
- Phase III clinical trial under preparation in Europe and the United States

Vienna, Europe, December 14, 2017 – Zytoprotec, a biopharmaceutical company developing innovative dialysis fluids, announced today that the United States Food and Drug Administration (FDA) has granted orphan drug designation to PD-protec®, the Company’s peritoneal dialysis fluid for the treatment of patients with end-stage renal disease (kidney failure).

Zytoprotec is currently preparing a pivotal Phase III clinical trial with PD-protec® in 300 patients suffering from end-stage renal disease in Europe and the United States.

Orphan drug designation is a special status granted by the FDA to treatments for rare diseases that affect fewer than 200,000 people in the United States. The orphan designation will provide Zytoprotec with several development incentives including market exclusivity for up to seven years upon FDA approval.

„Attaining orphan designation for PD-protec® is an important milestone in our efforts to bring this novel PD fluid closer to market approval,” said Bernhard Zinner, Managing Director of Zytoprotec. „Chronic kidney failure is a life-threatening condition that puts an immense burden on patients and also on the health-care system. We believe that PD-protec® has the potential to improve the treatment in an area that has seen little meaningful innovation in decades.‟

„In a recent Phase II clinical study PD-protec® successfully met both endpoints and we are eager to corroborate the benefits of this novel dialysis fluid in a pivotal Phase III trial in Europe and in the United States,” Bernd Seibel, Managing Director of Zytoprotec, added.

About PD-protec®

PD-protec® is being developed to prevent severe complications currently associated with peritoneal dialysis (PD). Essential ingredients of all available PD fluids, or solutions, inherently damage abdominal tissue. This is a major impediment to a more widespread use of peritoneal dialysis. PD is a cost-effective form of dialysis that patients can perform at home, at work or even while traveling. Typically, peritoneal dialysis allows them to lead more mobile and independent lives compared to hemodialysis, where patients are required to visit a treatment center for 4 to 5 hours, 3 times a week. PD-protec® is a PD solution that includes a cytoprotective compound (Alanyl-Glutamine) to protect peritoneal tissue, thus prolonging the time patients can stay on PD.

The product has successfully completed Phase II clinical development. In this best-in-class Phase II trial, PD-protec® demonstrated significant improvement of important biomarkers of peritoneal membrane integrity and peritoneal immune competence, thereby confirming the potential of PD-protec® to reduce clinically important complications such as peritonitis and dialysis failure in PD.
About Zytoprotec

Zytoprotec is a biopharmaceutical company based in Austria, Europe. Its lead product, PD-protec®, is being developed to improve the treatment of patients with end stage renal disease (kidney failure). The beneficial effects of Alanyl-Glutamine in peritoneal dialysis have been discovered by one of Zytoprotec's founders, Prof. Dr. Christoph Aufricht.

For more information on Zytoprotec and its cytoprotective approach please visit www.zytoprotec.com

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