

## **PharmaSens Earns ISO 13485 Certification and Drives Diabetes Care with Innovative niia essential Insulin Patch Pump System**

- **PharmaSens is spearheading advancements in diabetes management with its niia essential Insulin Patch Pump System**
- **Backed by a strong patent portfolio and a team of highly experienced professionals the company stands as a leader in diabetes care innovation**
- **niia essential Insulin Patch Pump System caters to the "almost pumpers" and is addressing a previously untapped \$10 billion market opportunity**
- **PharmaSens remains well-aligned for an FDA submission slated for late 2023**

*Biel/Bienne (Switzerland), November 10, 2023*

PharmaSens AG, a privately owned Swiss company dedicated to expanding access to insulin pump therapy, has been granted the ISO 13485 certification by TÜV Süd. This certification encompasses the entire process of designing, developing, manufacturing, and distributing insulin infusion pumps and accessories, as well as associated end-user software in the field of diabetes care. ISO 13485 is an internationally recognized standard that outlines the prerequisites for organizations to establish and execute a quality management system (QMS). This QMS demonstrates their ability to consistently deliver medical devices and related services that adhere to customer expectations and regulatory requirements.

Marcel Both, CEO of PharmaSens, expressed his pride in the recent attainment of the ISO 13485 certification from TÜV Süd, stating, "This certification underscores our unwavering dedication to delivering top-tier products and services to our prospective clients."

Employing an industry-standard Product Development Process (PDP), spanning five distinct phases, and encompassing eleven workstreams, PharmaSens remains well-aligned for an FDA submission slated for late 2023. Marcel Both expressed his confidence in the company's readiness for this milestone, stating, "We are very confident that we will achieve a successful and timely FDA submission." And he added: "Now that we have received the ISO 13485 certification, we are well prepared and ready to initiate the CE mark application. However, our first priority remains a successful FDA submission."

Backed by a strong patent portfolio and a team of highly experienced professionals who have played pivotal roles in the development of multiple insulin pump generations, PharmaSens stands as a leader in diabetes care innovation. The company has developed a platform of different products that enable a variety feature integration, as for example paving the way for the integration of a glucose sensor for a true all-in-one device. PharmaSens' insulin patch pumps are engineered to provide precise and dependable medication delivery, while its accessories aim to enhance patient comfort and convenience. The company's patent portfolio encompasses five distinct proprietary product technologies and six strategically vital intellectual properties.

PharmaSens' first product, the niia essential Insulin Patch Pump System, is a basal-bolus patch pump, known for its streamlined design, making it exceptionally user-friendly. It seamlessly combines the ease of an insulin pen with the advantages of a sophisticated insulin pump. One of its standout features is the

innovative 3ml reservoir, which not only offers an extended usage period and extended access to reimbursed patch pump therapy, but also positions niia essential as one of the most compact patch pumps on the market. Furthermore, niia essential Insulin Patch Pump System incorporates a distinctive automatic needle insertion mechanism that safeguards the 90° steel needle prior to each use. Additionally, the forward-thinking semi-reusable concept aligns with the principles of cost-efficiency and sustainable product design, meeting the requirements for a more environmentally friendly approach.

### **About PharmaSens**

PharmaSens AG, a privately owned Swiss company, is dedicated to simplifying diabetes management, and broadening the reach of insulin pump therapy. The company's team comprises skilled professionals with a wealth of experience in diabetes care, having contributed to the development of multiple insulin pump generations. PharmaSens possesses a distinctive patent portfolio encompassing five proprietary product technologies and six strategically significant intellectual properties, all with global filings and granted status. Their debut offering, the niia essential Insulin Patch Pump System, is specifically tailored to meet the unmet needs of the "almost pumpers," representing a market opportunity worth an estimated \$10 billion that has remained untapped.

### **Media Contact:**

Marcel Both, CEO: [media@pharmasens.com](mailto:media@pharmasens.com); +41 78 659 27 30

Daniel Piller, Partner Dynamics Group; [media@pharmasens.com](mailto:media@pharmasens.com); +41 79 341 36 78