

PharmaSens Successfully Submits FDA Approval Application for Groundbreaking Insulin Pump System

- **FDA application for the 'niia essential' marks a major milestone in advancing insulin pump technology with its innovative, patient-centric design**
- **'niia essential' Insulin Patch Pump System targets the significant yet underserved 'almost pumpers' market, tapping into an estimated \$10 billion opportunity**
- **Engaging in strategic financial discussions, PharmaSens prepares for a dynamic market entry and continuous development in diabetes care technology**

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PharmaSens AG, a privately owned Swiss company dedicated to expanding access to insulin pump therapy, today announced the successful and timely submission of its application for FDA approval for the revolutionary "niia essential" insulin pump system. This milestone follows the recent achievement of the ISO 13485 certification, encompassing the entire process of designing, developing, manufacturing, and distributing insulin infusion pumps and accessories.

The "niia essential" system, the first of a three patch pumps and designed with patient-centricity and ease of use at its core, is poised to address unmet needs in the diabetes management market. Marcel Both, CEO of PharmaSens, stated, "Our submission to the FDA is a pivotal step towards making advanced diabetes care accessible. We are committed to transforming the experience of diabetes management through our innovative technology." With a robust patent portfolio and a seasoned team, PharmaSens is well-positioned to meet the stringent requirements of the FDA. The "niia essential" system stands out for its user-friendly interface and potential to enhance the daily lives of diabetes patients worldwide.

"As we anticipate a favorable review from the FDA, PharmaSens is gearing up for the market launch of our 'niia essential' insulin pump system. Recognizing the importance of a strong partnership for successful market entry, PharmaSens is engaging in trade sale discussions," said Marcel Both. "The current interest in PharmaSens suggests a perfect timing. Such a move would enable the new owner to focus on a market entry strategy with our scalable and soon-to-be-approved product. At PharmaSens, our strengths lie in developing, manufacturing, and supporting innovative insulin pumps. A sale at this juncture allows us to concentrate on these areas and advance our product pipeline, including the development of a 'closed-loop' system and an integrated CGM-sensor and pump."

About the niia essential Insulin Patch Pump System

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 and MedTech device engineering, having contributed to the development of multiple insulin pump generations. Over the course of several years of innovative research and development, PharmaSens has built a distinctive international patent portfolio protecting the inventive concepts realized in their products. 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.

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