SenzaGen broadens non-animal offering for medical devices with more tests and tailored consulting services – strengthens market presence and realizes synergies from acquisition

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Starting in February 2022, SenzaGen provides an expanded and more complete in-vitro toxicology test offering for the large medical devices market. This broadening is a result of SenzaGen's acquisition of Italian company VitroScreen, which took place in November 2021. Combining their collective expertise and sales activities for both companies' non-animal test and service offerings serve as additional enablers for faster and more cost-effective expansion in the medical devices market, whose interest in non-animal solutions is growing as regulatory changes come into effect.

The broadened offering includes non-animal tests for biological evaluation, identification of medical devices and classification under the EU Medical Device Regulation (MDR 2017/745), and tailored expert consulting services. The updates to the ISO standards regulating safety testing for skin irritation and skin sensitization were recently published and recommend avoiding animal testing and instead using non-animal methods, which generates greater interest in this segment. The tests are based on state-of-the-art technology on genomics, machine learning and 3D human tissue models.

"SenzaGen and VitroScreen are taking a key step in their integration strategy by starting up sales activities for a joint offering. The acquisition of VitroScreen further increases our expertise in the field of in vitro toxicology and enables us to offer an expanded range of tests and services for medical devices, giving us access to a much larger market. We see rapid growth in interest from the medical devices market, especially in Europe, where work on transitioning to non-animal methods has advanced the furthest, and we expect to increase sales to companies in this target group," says Peter Nählstedt, President and CEO of SenzaGen.

The expanded offering includes skin irritation and cytotoxicity tests and services for medical device that complement SenzaGen's innovative GARD® platform of skin sensitization tests, whose inclusion in the ISO 10993 standard series is generating increased interest. SenzaGen is the first company to offer the three tests forming a complete in vitro package for a part of the risk assessment that all classes of medical devices must undergo before being brought to market. In addition, irritation tests in other tissues are offered.

The offering also includes consulting services such as in vitro testing strategies and pharmaco toxicology expert support on how to combine tests for each customer project under the MDR requirements. Additionally, the expanded offering features pre-clinical services for substance-based medical devices which are based on 3D human tissue models.

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About us

SenzaGen aims to be a leader in non-animal toxicology testing, driving the transition from animal testing to methods better suited to reflect human biology. The Company provides high-performance, non-animal test methods and innovation and consulting services based on state-of-the-art technology. Non-animal methods are more effective, more accurate and less expensive than traditional animal-based methods while also helping to reduce the number of laboratory animals. The Company has a growth strategy centered around continued commercialization of its proprietary GARD® test platform, expansion of its test portfolio and evaluation of acquisition opportunities of profitable and growing companies with complementary offerings. SenzaGen has its headquarters and GLP-certified laboratory in Lund, Sweden and subsidiaries in the US and Italy. For more information, please visit: www.senzagen.com.

SenzaGen is listed on Nasdaq Stockholm First North (ticker: SENZA), and FNCA Sweden AB, +46(0)8-528 00 399, info@fnca.se, is the company's Certified Adviser.

Attachments

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