Lund, August 27, 2019

SenzaGen expands its product portfolio with a test for the Medical Devices market

SenzaGen today announced an expansion of its product portfolio with the launch of GARD™skin Medical Device – a new test to assess whether medical devices can cause skin allergies. Regulatory changes are already underway in the market, which will mean increased requirements for product safety. Together with the ongoing trend towards reducing animal testing in general, this increases the need for alternative testing methods. The launch of GARD™skin Medical Device will take place at the Eurotox congress in Helsinki on September 8-11, 2019.

The Medical Devices market is a large and very interesting market for the company. The target group for GARD™skin Medical Device is initially medical device companies that perform sensitization tests during their product development and have high quality and safety requirements for the risk assessment related to their materials. With this test, SenzaGen meets the needs of an additional customer group and strengthens its position in the global market for cell-based *in vitro* tests.

"With our test method we can offer the industry a cost efficient and better method which gives more accurate results without animal testing. By identifying strategically important product development customers, we can already now generate sales and help them prepare for when the new regulations are in place. The ultimate goal is to see the test method being part of the international ISO standard so that it can be used instead of animal testing when registering medical devices," says Axel Sjöblad, CEO of SenzaGen.

Increased demand for care and technological advances drive the need for a new generation of medical devices. The global Medical Devices market is estimated to be worth $410 billion in 2023 with an annual increase of 4.5% from 2018 to 2023. All medical devices that come into physical contact with the patient must undergo risk assessment for allergy before they can be sold. Since there are currently no validated alternative methods, most tests are currently done on guinea pigs, despite varying results using that method. Within the EU, a change in the regulatory framework (MDR) is underway which will lead to an increased demand for quality, safety and documentation of the products. In parallel, the new ISO standard for biological evaluation of medical devices advocates alternatives to animal testing. When the new regulations have come into force, SenzaGen estimates the value of its addressable market in Europe and the US to approximately SEK 1.6 billion.

As part of the launch, the company will also be presenting at the NABS conferences in Minneapolis, USA on September 18 and Symbioteq Biocompatibility of Medical Device in Gothenburg on October 1-2, as well as holding an online webinar in November.

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About GARD®

GARD® consists of a group of tests for analyzing chemicals' ability to start an allergic reaction in humans. The tests are performed on human cells in test tubes (*in vitro*) in combination with artificial intelligence. By analyzing hundreds of markers, GARD® generates large amounts of data and delivers results with over 90 percent accuracy. This can be compared to today's standard method - tests on animals - which only achieves 70-75 percent precision. The product portfolio consists of tests for skin and respiratory allergy: GARD™skin, GARD™air, GARD™potency and GARD™skin Medical Device.

About SenzaGen

SenzaGen's technology enables replacement of animal experiments with genetic testing in test tubes for determining the allergenicity of the chemicals we come into contact with in our daily lives, such as those in cosmetics, pharmaceuticals, food products and dyes. The company's patented tests are the most reliable on the market and provide more information than traditional evaluation methods. We ourselves sell the tests in Sweden and the USA, and we sell through partners in several other countries. Over the next few years the company will expand geographically, make alliances with more distribution partners and launch further unique tests. SenzaGen has its headquarters in Lund in Sweden and a subsidiary in the USA. For more information, please visit www.senzagen.com.

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