SenzaGen targets the growing medical device market

Lund, August 29, 2018 - SenzaGen (Nasdaq First North: SENZA) announces today that the Company is now expanding its market focus to the medical device market. This market is in strong growth as a result of a growing and aging population in combination with a new regulatory framework for medical devices and increased quality standards.

Today, SenzaGen focuses on the chemicals, cosmetics and pharmaceutical markets for its global commercialization of GARD®, an *in vitro* platform for risk assessment of chemicals. Now, the Company has decided to further expand its market presence and will also focus its efforts on the global market for medical devices.

"We see significant opportunities in the medical device market. Large underlying growth combined with a willingness to use *in vitro* tests to assess the risk profile of medical devices and a new regulatory framework means that the medical device market will be a natural next step for SenzaGen," says Anki Malmborg Hager, CEO of Senzagen.

The global medical technology market is estimated to be worth $410 billion in 2023 with an annual increase of 4.5% in 2018-2023. All medical devices that come into contact with the patient must be assessed for allergy before they can be sold. The market potential of testing and risk assessment of medical devices is therefore very large and increasing. At the moment, changes are made in the EU regulatory framework for medical devices while the global ISO Standard ISO 10993 for the approval of medical devices is updated. So far, ISO 10993 has required tests on guinea pigs for sensitization, but work is ongoing to update the standard to include animal-free tests, which SenzaGen can capitalize on.

In order to increase the introduction pace, the Company has signed a cooperation agreement with Research Institutes of Sweden (RISE) in order to adapt GARD® for testing medical devices. Furthermore, Eurofins, licensee to GARD®, is a major player in the medical devices market and will therefore be able to expand its offer to this market.

A first step in the adaptation of GARD® for medical devices will be presented as a poster at the EUROTOX conference in Brussels, 2-5 September 2018.

For more information, please contact:

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About GARD®

GARD® is a group of tests for assessing chemical skin sensitizers. The tests make use of genetic biomarkers for more than 200 genes which cover the entire immune reaction and are relevant to predicting the risk of hypersensitivity. The tests have over 90 percent reliability. This compares with the current predominant test method, experiments on mice, which has an accuracy of 70-75 percent. SenzaGen's tests are also capable of measuring the potency of a substance's allergenic properties. Consequently, GARD® tests provide a much more comprehensive basis for determining whether a substance should be classified as an allergen than current testing methods.

About SenzaGen

SenzaGen makes it possible to replace animal experiments with in vitro genetic testing to determine the allergenicity of the chemicals we come into contact with in our daily lives, such as for example 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 San Francisco, USA. For more information visit **www.senzagen.com**

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SenzaGen AB are listed on Nasdaq First North in Stockholm and FNCA is the company's Certified Adviser. For more information, please visit www.senzagen.com

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