

SenzaGen's final validation report of GARDskin™ submitted to regulatory authorities – reveals highest test prediction accuracy in the field

Lund, January 12, 2018 - SenzaGen (Nasdaq First North: SENZA) announces today that the company has submitted the final report for the validation of GARDskin™ to the regulatory authorities. Global regulatory approval and recommendation by ECVAM and OECD on the use of GARDskin is expected in April 2019. The final result presented in the report shows an unprecedented over all prediction accuracy of 93,8% in determining whether chemical substances are at risk of causing allergies. This proves that GARDskin™ outperforms all current available validated methods.

The analysis of the data has been performed by an independent validation statistics consultant, according to the regulatory requirements. This analysis is the base for the official report now sent in to ECVAM. The data shows that the mean accuracy from all three independent laboratories (Eurofins BioPharma Product Testing in Germany, Burleson's Research Technologies in the United States and SenzaGen's own laboratory in Lund) is very high, reaching an accuracy of 93,8%.

The validation has included a large number of coded chemicals unknown to the validation laboratories, to enable the blinded testing demanded in this process. All laboratory results have been provided in a blinded manner to an external validating statistics consultant, who has now decoded the identity of the chemicals to compare the GARD classification performed at each lab, and analysed the prediction accuracy of GARD in classifying compounds as non-sensitizers or sensitizers. The validation report also includes data on the robustness of the test platform and its transferability.

The results in this report constitutes the basis for the evaluation of SenzaGen's tests in the ECVAM Scientific Committee and within the OECD for regulatory approval and Test Guideline recommendation on the use of GARDskin. The regulatory decision from OECD is expected in April 2019. GARDpotency™, which is based on the same biological platform, is being validated in parallel with GARDskin™, and is thus expected to be approved and recommended at the same time.

“These excellent validation results underpin the potential for GARD testing to become a game changer in *in vitro* allergy testing. We have long been aware of its high performance, and the validation now also provided by independent laboratories is of course very satisfying. Importantly, the validation has highlighted the simplicity of assay transfers to other labs. This adds to the confidence of further laboratories around the world to set up our unique assay,” says Anki Malmberg Hager, CEO of SenzaGen.

A comprehensive report of the results will be presented at the Society of Toxicology's 57th Annual Meeting 11-15 March in San Antonio, US.

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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 up to 90% reliability. This compares with the current predominant test method, experiments on mice, which has an accuracy of 70-75%. 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