Positive scientific ESAC opinion on GARD®skin paves the way for OECD validation and opens new commercial opportunities

Lund, July 26, 2021

EURL ECVAM, the EU Reference Laboratory for alternatives to animal testing, has announced that ESAC, their scientific advisory committee, has issued a positive opinion on the GARD®skin test method. Depending on the regulatory context, positive results obtained with GARD®skin can be used stand-alone to identify skin sensitizers and the method is recommended to be adopted as an OECD Test Guideline for skin sensitization. The announcement marks a major milestone in the regulatory approval process for GARD®, opening up new commercial opportunities for the company.

ESAC has now completed its scientific evaluation, which shows that the GARD®skin assay meets the EURL ECVAM requirements for reliability in testing in preparation for regulatory filing. This means that the test is science- and evidence-based, can be transferred to other laboratories, and delivers the same performance regardless of who conducts the test. In their report, ESAC states that GARD® skin can, depending on the regulatory context, be used as stand-alone for positive results when identifying skin sensitizers, which means that no additional testing is needed. A negative result must be considered together with additional evidence.

"This report is a key milestone for the company and I am very pleased that we have received a positive ESAC opinion for GARD®skin as the first genomic test for identifying skin sensitizers. I would like to thank EURL ECVAM and ESAC for their professionalism and a well-written report," says Axel Sjöblad, CEO of SenzaGen. "According to the positive opinion, ESAC recommends that OECD include GARD®skin on their list of internationally agreed test methods. Furthermore, it means that our groundbreaking GARD®-technology, which is based on both genomics and machine learning, has now been validated by an objective group of international experts. With the final OECD approval in place, we will be able to offer the GARD®-tests to a significantly broader customer base in various industries, such as cosmetics and chemicals in the EU, the US and Asia. This paves the way for an accelerated market growth and from now on we will refer to ESAC's positive opinion in all our external communications," Axel Sjöblad continues.

"When an international regulatory authority approves such a technologically advanced test system as GARD®, it sends a strong message," says Henrik Johansson, Chief Scientist at SenzaGen. "The positive news confirms that GARD® is a science-based, and a technically sound method for the prediction of skin sensitization. With this endorsement, a range of technical components such as high-dimensional predictive modeling and cloud-based analytic tools are also introduced as novelties in regulatory toxicology. This establishes SenzaGen as a strong player in the market, especially in the development of future tests based on our key competences," he says.

Furthermore, ESAC considers that GARD®skin and GARD®potency are functional and valid test methods ready for use in industrial screening applications. SenzaGen is now building more data for GARD®potency regarding predictivity and reproducibility, so that GARD®potency can also be used in a regulatory context.

The ESAC opinion
ESAC's opinion is available on the JRC Publications Repository webpage: https://publications.jrc.ec.europa.eu/repository/handle/JRC125963

Webcast
SenzaGen invites media and investors to a webcast on July 29 at 15.00 CEST, when CEO Axel Sjöblad and Chief Scientist Henrik Johansson will comment on the ESAC opinion. The webcast will be held in English. It will start with a presentation which will be followed by a Q&A session.

To participate in the webcast, register well in advance using the following link: https://attendee.gotowebinar.com/register/8998421169786434061

After the live broadcast, a recording will be available on the company's website.

The GARD regulatory process
The GARD regulatory process is underway for the GARD® test method. The evaluation has been conducted by the EU Reference Laboratory for alternatives to animal testing (EURL ECVAM) on behalf of the OECD. A key step in the process is evaluating whether the tests are scientifically evidence based, can be set up in other laboratories (transferability) and can deliver the same performance regardless of who conducts the tests (robustness). For this purpose, SenzaGen has conducted a large validation study and its results have been evaluated by EURL ECVAM's Scientific Advisory Committee (ESAC). Following the scientific evaluation, ESAC has issued a recommendation to the OECD, which will be the foundation for issuing a Test Guideline. An issued OECD Test Guideline will allow customers to use GARD® test results in product registrations. SenzaGen has prepared a Test Guideline draft and is in regular contact with both the Swedish Chemicals Agency and OECD.

Contacts

Axel Sjöblad, CEO, SenzaGen AB
Email: axel.sjoblad@senzagen.com| Mobile: +46 705-35 93 51

Tina Dackemark Lawesson, VP Marketing & Communications
Email: tina.lawesson@senzagen.com| Mobile: +46 708-20 29 44

About us

SenzaGen is a Swedish biotech company that provides state-of-the-art non-animal tests for assessing a substance's allergenicity. The GARD® test method combines genomic data from human cells with machine learning for a unique capability to identify and analyze whether a chemical could cause allergic reactions on the skin or in the respiratory tract. With excellent predictivity, GARD® meets needs in several industries and helps companies develop, produce and deliver safer, ethical

and more sustainable products. GARD® tests are performed in SenzaGen's GLP-approved lab and by select partners in Europe and the US. SenzaGen has its headquarters in Lund, Sweden and a subsidiary in the US. 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.

This information is information that SenzaGen is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2021-07-26 08:00 CEST.

Attachments

Positive scientific ESAC opinion on GARD®skin paves the way for OECD validation and opens new commercial opportunities