OECD GARD® adoption update: The COVID-19 pandemic reschedules the scientific ESAC opinion on GARD®

Lund, November 11, 2020

EURL-ECVAM has informed SenzaGen that due to COVID-19, the next plenary meeting for its Scientific Advisory Committee (ESAC) has been rescheduled from November 2020 to March 2021. The change delays the expected ESAC opinion on the GARD®skin and GARD®potency assays. The OECD adoption of GARD may not take place in 2021.

"It is unfortunate that COVID-19 delays the ESAC GARD opinion, but I understand the decision considering the current circumstances. During the year we have had productive and fruitful virtual meetings with ESAC Working Group representatives and members from EURL ECVAM's Joint Research Center. We have answered to their questions and made all necessary information available to ensure that they are on top of the GARD review and hope for an endorsement in March 2021. Looking ahead, the GARD OECD adoption may not take place in 2021. Despite COVID-19, we have seen an increasing demand for our services and during the first six months we doubled sales compared to the same period last year. We will continue to work towards our 2022 break-even target by addressing customers and industries that benefit from the high accuracy of the GARD assays and the additional services we can offer without the need of a GARD OECD adoption", says Axel Sjöblad, CEO of SenzaGen.

The following information has been published today on the EURL ECVAM TSAR webpage https://tsar.jrc.ec.europa.eu/test-method/tm2011-09:

"Third meeting of the ESAC Working Group on the GARD to discuss additional information provided by the test submitter. Due to the situation with the COVID-19 pandemic, the ESAC face-to-face plenary meeting initially scheduled for November 2020 has been postponed to March 2021. The November meeting has been converted into a virtual meeting of the ESAC Working Group on the GARD to grant more time to the experts to discuss the GARD submission due to the impossibility of organising a face-to-face meeting. The Working Group is aiming at finalising their peer-review report with a view of discussing and possibly endorsing the ESAC Opinion in March 2021."

The GARD regulatory process

The GARD regulatory process is underway for the GARD®skin and GARD®potency tests. The review is being 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 are being evaluated by EURL ECVAM's Scientific Advisory Committee (ESAC). Following the scientific evaluation, EURL ECVAM will issue 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.

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About us

SenzaGen is a Swedish biotech company that provides state-of-the-art animal-free 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 2020-11-11 18:10 CET.

Attachments

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