Pivotal Flavocide® extended one-generation reproductive toxicity study in rats (OECD 443) underway

Highlights

- **This study forms a core element of Bio-Gene's Flavocide® active ingredient registration data package for Australia and other international jurisdictions**
- **Provides pivotal reproductive and developmental safety data for Flavocide®**
- **The dose range-finding study, which determined the doses to be included in the main study, has been completed and the preliminary report of the main study is scheduled to be received in September 2026**

Melbourne, Australia: Bio-Gene Technology Limited (ASX:BGT or 'Bio-Gene' or 'the Company'), an Australian company developing the next generation of novel insecticides derived from nature, is pleased to announce that the pivotal Flavocide extended one-generation reproductive toxicity study is underway. This study is required to support international submissions for regulatory approval and is designed to assess potential effects of Flavocide, Bio-Gene's new insecticidal active ingredient, on fertility, reproductive performance and developmental outcomes in rats (**OECD 443 Study**).

The results will inform key aspects of Bio-Gene's dossier of mammalian toxicology data to be submitted to the Australian Pesticides & Veterinary Medicines Authority (**APVMA**) in Australia in support of its application for the registration of Flavocide as an active constituent for use in products for the control of insect pests. Successful completion of this study will be a significant milestone in advancing Flavocide toward registration and commercialisation.

Summary of the OECD 443 Study

This OECD 443 Study is designed to evaluate potential reproductive and developmental effects in rats following prenatal and postnatal exposure to Flavocide and to evaluate systemic toxicity in parental animals and their offspring, including pregnant and lactating females.

In this study, Flavocide will be administered to adult male and female rats in the diet before and after mating, and to females during pregnancy and lactation. Offspring will be monitored from birth through weaning, with a subset continuing on the treated diet into adulthood to assess growth and general health over time, including targeted examinations of reproductive organs and other key tissues.

This study is being conducted by a Contract Research Organisation (**CRO**) in accordance with OECD guidelines and Good Laboratory Practice (**GLP**).

Key study parameters:

Study name:	OECD 443: Extended One Generation Reproductive Toxicity Study (Rat)
Study objectives:	Evaluate potential effects of dietary exposure to Flavocide on rat reproductive performance, fertility, development, and systemic toxicity across parental (F0) and offspring (F1) generations.
Test material:	Flavocide technical material (≥96% flavesone)
Animal type(s):	Rat (*Rattus norvegicus*), Wistar strain, both sexes
Protocol summary:	This is a GLP-compliant OECD Test Guideline 443 study (including initial dose range finding arm) with dietary administration of Flavocide, including pre-mating, mating, gestation, lactation, and post-weaning phases. Evaluation includes reproductive performance, developmental outcomes, systemic toxicity, and relevant clinical, pathological and histopathological assessments.
Study end-points:	Reproductive performance (mating, fertility, gestation, litter size, pup viability); developmental and growth parameters; clinical observations; body weights; food consumption; organ weights; gross necropsy; histopathology; estrous cyclicity; sperm parameters; and selected hormonal assays
Reporting & key dates:	The dose range-finding OECD 443 study (**DRF Study**) to identify the appropriate dose of Flavocide to be ad`ministered to the animals in the main OECD 443 Study has been completed. The in-life phase of the main OECD 443 study (**Main Study**) is expected to finish during July 2026, with the preliminary report scheduled to be received during September 2026 and final report during November 2026.

Relevance of the OECD 443 Study

The OECD 443 Study is an internationally recognised toxicity study used globally[1] to evaluate potential effects of a test substance (i.e. Flavocide) on fertility, reproductive performance and

[1] The protocol used for this study complies with the OECD Test Guideline No. 443 'Extended One-Generation Reproductive Toxicity Study' (2025). This guideline forms part of the OECD's Mutual Acceptance of Data (MAD) system, which provide guidelines for the testing of chemicals using a collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories. These guidelines provide a common basis for co-operation between regulatory bodies across the 38 OECD member countries (and a further seven non-member countries) to assess the toxicity of new chemical substances.

offspring development in laboratory animals (rats). The study includes evaluation of outcomes following prenatal and postnatal exposure and assessment of systemic toxicity in parental animals and offspring.

The data generated will be suitable for submission to regulatory bodies operating under the OECD's Mutual Acceptance of Data arrangements (**OECD MAD framework**), including OECD member countries such as Australia, New Zealand, USA, Canada, Japan, the United Kingdom and many European countries. The data will also be accepted in non-member countries that are full adherents to the **OECD MAD framework**, including South Africa, Singapore, India, Brazil, Argentina, Malaysia and Thailand.

The information will also be used in regulatory risk assessment in various other countries, including to confirm the safe use of Flavocide-based products and the consideration of human health and the environment.

The OECD 443 Study will generate:

- data for assessing the long-term and reproductive toxicity potential of Flavocide
- information to assist in defining safe exposure limits and guide instructions for product use
- insights required by regulators to evaluate safety for people and animals in the area of use

Tim Grogan, Managing Director & Chief Executive Officer for Bio-Gene said:

The regulations governing the development and approval of Flavocide as a new insecticide require that Bio-Gene generate and submit data demonstrating it is safe to animals and the environment. This extended one-generation reproductive toxicity study is the longest and most complex study we are required to undertake. This study has required significant preparation and planning by our development team.

I am delighted that we have completed the dose range finding study, which was a necessary stage prior to commencing the main study. We are looking forward to receiving the results of the main study, which are scheduled to be received in September 2026."

Relationship to other studies

The OECD 443 Study is one of several core toxicity studies required to be included in the Flavocide regulatory dossier. It builds on shorter-term mammalian toxicology work in rats and other test species already completed by Bio-Gene, such as acute and sub-chronic toxicity tests, and complements other ongoing and planned long-term toxicity studies. Together, these studies form the comprehensive mammalian data package needed to demonstrate the suitability of Flavocide for regulatory approval and commercial use.

Flavocide Background and Study Context

Flavocide is a novel insecticide that is identical to flavesone, a naturally occurring plant compound present in some eucalypts. Bio-Gene has developed a proprietary process to synthesise this molecule and produce it in commercial quantities. Bio-Gene owns all intellectual property created by its contractors relating to the synthesis of Flavocide.

Flavocide exhibits a new mode of action – that is, the way it controls or knocks down an insect - and is able to overcome insect resistance to many currently used insecticidal products. Bio-Gene is developing Flavocide to address the global problem of insecticide resistance in the areas of public health, crop protection, grain storage and consumer applications.

The Company's business model involves entering into licensing arrangements with commercial partners internationally to formulate and develop insecticidal products that contain Flavocide. Bio-Gene will then be entitled to receive up-front and milestone payments and then royalties from its commercial partners upon sale of these new products. Bio-Gene's business model also includes the supply of Flavocide to these partners in commercial quantities under a commercial supply agreement.

Approved for release on ASX by Bio-Gene Board of Directors.

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About Bio-Gene Technology Limited

Bio-Gene is an Australian company developing novel bio-insecticides to address the global challenges of insecticide resistance. Its unique products are based on a naturally occurring class of compounds proven to overcome insecticide resistance to control pests with minimal impact on human health and the environment.

Bio-Gene's products have multiple applications across crop protection, grain storage, public health and consumer uses. They provide new options derived from nature to meet market demand for effective and safe pest management solutions.

www.bio-gene.com.au

About this announcement

This announcement has been prepared in accordance with the AusBiotech *Code of Best Practice for Reporting by Life Sciences Companies* (2nd Edition), 2013. The objectives of this Code are to:

a. provide a reference tool to guide public Australian life science companies in effective and informative communication to the market according to a guidance framework;
b. incorporate international best practice in reporting, and thus maintain and enhance the reputation, integrity and credibility of the Australian life science sector; and
c. provide information to investors about the disclosure framework that identifies the key drivers of value for life science companies, supporting more informed investment decisions.
