

ASX Release

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ZOLPIMIST LAUNCH AUSTRALIA

MELBOURNE, AUSTRALIA 22 June 2022: Arovella Therapeutics Ltd (ASX: ALA), a biotechnology company focused on developing its invariant Natural Killer T (iNKT) cell platform and its oral spray delivery technology to treat cancer and conditions that affect the central nervous system, announces that STADA Australia has initiated its commercial launch for ZolpiMist (zolpidem tartrate), a product indicated for the short-term treatment of insomnia in adults.

On 29 July 2020¹, Arovella announced that the Therapeutics Goods Administration (TGA) approved the registration of Arovella's most advanced product, ZolpiMist, for the short-term treatment of insomnia in adults. Subsequently, on 24 August 2021², Arovella announced that it entered into a licence and distribution agreement with STADA Australia. Following successful manufacturing of the product, STADA have initiated their commercial launch of the product in Australia.

Under the terms of the agreement, Arovella will coordinate manufacturing of the product through its Australian manufacturer. Arovella is in the process of implementing a more economical, elegant, and user-friendly child resistant lock (CRL). Arovella will receive a milestone payment of \$40,000 upon the anticipated TGA approval of the new CRL. The CRL is expected to be implemented from the second batch of product manufactured. Once the new CRL has been implemented, in addition to supply price, Arovella will receive a 10% royalty on net sales of the product.

STADA also has an option to commercialise the product throughout New Zealand and is considering expanding its footprint across additional territories.

Arovella's CEO and MD, Dr Michael Baker, commented "This is an exciting milestone for Arovella. We expected the product to be commercialised in the third quarter of 2022 and we have achieved that milestone early. We see ZolpiMist as an important product to assist with sleep, particularly with the lingering effects of the COVID-19 pandemic. It is due to the hard work of our team and our manufacturing partner that we have been able to achieve this milestone. We look forward to continuing and expanding the partnership with STADA."

For and on behalf of the Board and for further information, please contact:

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¹ Refer to ASX announcement 29 July 2020 'TGA Approval Granted for ZolpiMist'

² Refer to ASX announcement 24 August 2021 'SUDA and STADA Australia Enter a Licence and Distribution Agreement for ZolpiMist'



NOTES TO EDITORS:

About Arovella Therapeutics Ltd

Arovella Therapeutics Ltd (ASX: ALA) is a biotechnology company focused on developing therapies to treat human disease. Arovella's two focus areas are oncology and conditions that impact the central nervous system. Arovella is developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers. Arovella is also developing its DKK1-peptide targeting technology licenced from MD Anderson to be used in conjunction with its iNKT cell therapy platform. The Company is developing low-risk oral sprays to reformulate existing pharmaceuticals. The potential benefits of administering drugs through the oral mucosa (i.e. cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. Arovella's product pipeline includes an oral spray for the platelet-lowering drug anagrelide to treat metastatic disease in the background of high platelets, and ZolpiMist™, a first-in-class oral spray of zolpidem tartrate to treat short-term insomnia. ZolpiMist is approved by the FDA, TGA and the Ministry of Health (Chile) and is marketed in the USA. Arovella has rights to the product outside of the US and Canada. Other products in development include oral sprays to treat migraine headaches, motion sickness, and drug-resistant epilepsy.

For more information, visit www.arovella.com

This announcement contains certain statements which may constitute forward-looking statements or information ("forward-looking statements"), including statements regarding negotiations with third parties and regulatory approvals. These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding actions of third parties and financial terms. These factors and assumptions are based upon currently available information and the forwardlooking statements contained herein speak only as of the date hereof. Although the expectations and assumptions reflected in the forward-looking statements are reasonable in the view of the Company's directors and management, reliance should not be placed on such statements as there is no assurance that they will prove correct. This is because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forwardlooking statements. These risks include, but are not limited to: uncertainties and other factors that are beyond the control of the Company; global economic conditions; risk associated with foreign currencies; and risk associated with securities market volatility. The Company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by Australian securities laws and ASX Listing Rules.