Clinuvel announces innovative melanocortin for new indications
Singaporean subsidiary VALLAURIX completes preliminary evaluation of VLRX001

**SUMMARY**

- Clinuvel expands pipeline with VLRX001 targeting skin disorders
- First therapeutic target: vitiligo (depigmentation disorder) as maintenance therapy following SCENESSE® (afamelanotide 16mg)
- Innovation is the result of collaboration between Clinuvel and the international research community
- Proprietary technology of VALLAURIX PTE LTD, a majority-owned Clinuvel subsidiary
- Recent clinical research has demonstrated a renaissance in the demand for novel melanocortin molecules

---

Melbourne, Australia and Zug, Switzerland, May 5 2015

Clinuvel Pharmaceuticals Ltd (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) today announced that its Singaporean subsidiary VALLAURIX PTE LTD has successfully completed initial in-vitro development of VLRX001, an innovative melanocortin analogue. VLRX001 is an addition to Clinuvel’s product pipeline alongside CUV9900 and SCENESSE® (afamelanotide 16mg), which was recently granted marketing authorisation by the European Commission for the rare disease erythropoietic protoporphyria (EPP).

**CLINICAL USE**

Formulation work will focus on the development of VLRX001 for topical self-administration by patients. The transdermal product will initially be evaluated as adjuvant maintenance therapy in the depigmentation disorder vitiligo. SCENESSE® is currently being evaluated as a subcutaneous medicinal product for repigmentation in vitiligo patients. Clinuvel published its first vitiligo results in 2012/13.

**RATIONALE FOR INNOVATION**

The VLRX001 development work was undertaken through Clinuvel’s majority owned Singaporean subsidiary, VALLAURIX and has leveraged the knowledge gained from long term experience with the clinical use of SCENESSE®.

It has long been acknowledged that melanocortins have a ubiquitous application in medicine. A renaissance in the demand for novel melanocortin molecules has been seen in clinical research, with more than 400 peer reviewed publications on the use of melanocortins over the past 24 months.

**KNOWHOW AND INTELLECTUAL PROPERTY**

Long term collaboration between Clinuvel’s scientific teams and research groups at prestigious institutes and universities led to the innovation of VLRX001.

VALLAURIX was able to harness the knowhow in melanocortins from IP and data generated in pharmacology studies and clinical use of SCENESSE® by Clinuvel's global teams. Overall, the development of VLRX001 is part of Clinuvel's life cycle management of its portfolio of products to ensure long term use and value of its technology and assets.

Patent applications on VLRX001 have been filed in the commercially relevant jurisdictions. Clinuvel will hold all rights to the final product and indications through VALLAURIX. Formulation work will commence this year.

VLRX001 is the second novel molecule to be evaluated by VALLAURIX. The first, CUV9900, has been developed as the first reference standard for evaluating pharmacological properties such as binding affinity, potency and cellular signalling.

**NOVEL PHARMACOLOGY**

VLRX001 is an addition to the family of melanocortin analogues which provoke increased and prolonged cellular activity. It contains a specific peptide sequence, designed to make it less susceptible to degradation than physiologic (natural) alpha-melanocyte stimulating hormone (α-MSH).
Many biotech and pharmaceutical companies commence the development of novel products but the complexity of human biological response and regulatory pathway see many of these fail along the road,” Clinuvel’s Acting Chief Scientific Officer, Dr Dennis Wright said. “It is a privilege to be part of a team which has delivered success through SCENESSE®.

"With VLRX001 we now have a logical follow-on product which we hope will act synergistically and be complementary to SCENESSE® in the treatment of vitiligo, a disease which is notoriously difficult to treat and deserves a range of therapeutic approaches,” Dr Wright said.

"Over the past year the management of Clinuvel have successfully transformed the Company from being an R&D house with a prospective regulatory outcome, to one with a commercial product lending its validation to second generation technology with wide applications,” Clinuvel’s Chairman, Mr Stan McLiesh said. “It has been Clinuvel’s key objective to retain the proprietary rights to the new technology.

“Our scientific and commercial progress stems from many years of interaction and dialogue with physicians and patients, and our teams have consistently taken a staunch approach to the opinions of global experts. I am certain that the corollary of Clinuvel’s work will result not only in clinical worth but in sustained shareholder value even in Australia, a market still lacking full appreciation of its biotech companies,” Mr McLiesh said.

### CLINUVEL’S PIPELINE

<table>
<thead>
<tr>
<th>Product</th>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCENESSE® in EPP (EU)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCENESSE® in EPP (USA/RoW)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCENESSE® in vitiligo</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CUV9900</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VLRX001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### REFERENCES


- End -

### Media enquiries

Lachlan Hay, Clinuvel (UK) Ltd. +44 1372 860 765 Lachlan.Hay@clinuvel.com
Nick Miles, Cabinet Privé de Conseils s.a. +41 22 321 4540 miles@cpc-pr.com
Ted Agne, The Communications Strategy Group Inc. +1 718 631 3117 edagne@comstragroup.com

### Investor enquiries

InvestorRelations@clinuvel.com
About Clinuvel Pharmaceuticals Limited
Clinuvel Pharmaceuticals Ltd (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) is a global biopharmaceutical company focused on developing drugs for the treatment of a range of severe disorders. With its unique expertise in understanding the interaction of light and human skin, the company has identified patient populations with a clinical need for photoprotection and another population with a need for repigmentation. These patient groups range in size from 5,000 to 45 million. Clinuvel’s lead compound, SCENESSE® (afamelanotide 16mg), a first-in-class drug targeting erythropoietic protoporphyria (EPP), has completed Phase II and III trials in the US and Europe, and has been approved by the European Commission for treating adults with EPP. Headquartered in Melbourne, Australia, Clinuvel has operations in Europe, the US and Singapore.

For more information go to [http://www.clinuvel.com](http://www.clinuvel.com).

Clinuvel is an Australian biopharmaceutical company focused on developing its drug SCENESSE® (afamelanotide 16mg) for a range of clinical disorders with unmet need. Pharmaceutical research and development involves long lead times and significant risks. Therefore, while all reasonable efforts have been made by Clinuvel to ensure that there is a reasonable basis for all statements made in this document that relate to prospective events or developments (forward-looking statements), investors should note the following:

- actual results may and often will differ materially from these forward-looking statements;
- no assurances can be given by Clinuvel that any stated objectives, outcomes or timeframes in respect of its development programme for SCENESSE® can or will be achieved;
- no assurances can be given by Clinuvel that, even if its development programme for SCENESSE® is successful, it will obtain regulatory approval for its pharmaceutical products or that such products, if approved for use, will be successful in the market place.

Level 5, 160 Queen Street T +61 3 9660 4900 www.clinuvel.com
Melbourne, Victoria 3000 F +61 3 9660 4999
Australia