Company Announcement
23rd April 2008
Melbourne Australia

Clinuvel's latest pharmacokinetic studies further validate human safety of CUV1647

Studies affirm safety and efficacy of Clinuvel's photoprotective drug when dosed variably

Clinuvel Pharmaceuticals Limited (ASX: CUV, XETRA: UR9; ADR: CLVLY) is pleased to announce the results of two further pharmacokinetic studies (plasma level of the active ingredient) confirming both additional safety of its photoprotective drug CUV1647, and pharmacodynamic effects (melanin activation of the skin) at a lower dose and upon frequent and repeated higher dose.

Two further studies (CUV007 and CUV009) were conducted at the Australian Centre for Pharmaceutical Research, University of Adelaide, under the supervision of principal investigator Associate Professor Dr Robert Milne. In total 16 humans were administered a bioabsorbable*, controlled release** implant loaded with CUV1647 subcutaneously (underneath the skin) and no serious adverse events were observed or reported. The studies are part of Clinuvel's ongoing development program for its photoprotective pharmaceutical product CUV1647. These results are consistent with those previously seen in Phase II clinical studies. The company aims to file for registration of CUV1647 as a photoprotective product in 2009.

The CUV007 study was a Phase I pharmacokinetic and melanogenic study of a new formulation of CUV1647 implants (10 mg). The study showed that the 10 mg CUV1647 implant used is safe and tolerable. Administration of the implant resulted in detectable CUV1647 levels in plasma from which the pharmacokinetic profile was determined. Pharmacodynamic analysis showed the 10 mg implant to have an affect on melanin expression at most anatomical sites, with melanin density increasing above baseline following treatment administration. There were no significant findings in any of the safety parameters monitored. (See Appendix 1)

The CUV009 study was a Phase I Pharmacokinetic study of two doses 28 days apart. This is the first continuous dosing study. Pharmacokinetics showed there was no significant difference in blood levels between the first (Day 0) 16 mg implant and the second (Day 28) 16 mg implant. Pharmacodynamics showed changes in melanin density over time were significant for all anatomical sites measured. There were no significant findings in any of the safety parameters monitored.

The superimposability of first and second dose profiles suggested there was no accumulation of CUV1647 and no effect of the first dose on the second dose pharmacokinetics (blood levels). The 16 mg implants did have a significant effect on skin melanin expression over time with melanin density values increasing above baseline at the anatomical sites analysed following treatment administration (See Appendix II).

The two studies build on Clinuvel's previous pharmacokinetic and pharmacodynamic study, CUV006 in 2007, and confirm the safety record of the drug to date.

Dr Philippe Wolgen, Clinuvel's CEO said:

"The significance of these particular results together with the study conducted in 2007 will serve to aid our chances to obtain regulatory approval for CUV1647. Our challenge is to optimize the effective pharmacological window of CUV1647 while increasing the confidence we have in the biological safety of our drug.

Two findings are seen from these studies:

(i) whereas until recently, Clinuvel has always administered the implant formulation every 60 days, today's clinical study results demonstrate that CUV1647 may be administered safely when the dose interval is reduced to every 28 days instead, that is without increasing and exceeding maximum human plasma (blood) levels.

(ii) by varying and reducing the dose interval, we have been able to demonstrate the tolerability of our drug CUV1647 beyond the clinical need."

* *Bioabsorbable may be defined as "fully degradable in the human body".*

** *Controlled release may be defined as "a technique or method in which active chemicals or drugs are made available to a specified target at a rate and duration designed to accomplish an intended effect".*

END

Appendix I (Following Code of Best Practice, ASX)

Study Title
CUV007. A Phase I study to assess the pharmacokinetics and melanogenic potential of a slow-release 10 mg implant of CUV1647 in healthy male volunteers.

Primary endpoints
a) Adverse events and changes in clinical measurements from baseline.
b) CUV1647 concentration-time profile.

Secondary endpoints
a) Changes in melanin density from baseline.

Blinding status
Open label.

Product Development Status
Good Manufacturing Practice (GMP) Standard.

Treatment method, frequency, dose levels
A single resorbable implant (10 mg CUV1647) administered subcutaneously.

Number of trial subjects
6 patients

Subject selection criteria
a) Healthy males, aged 18-45 years, with Fitzpatrick skin types I, II or III and no significant medical conditions or organ dysfunction.

Trial location
Single centre,
Centre for Pharmaceutical Research, Clinical Trials Unit, Sansom Institute,
University of South Australia, Adelaide.

Duration of the trial
60 days

Trial standard
In compliance with Good Clinical Practices (GCP) and ICH guidelines.

Appendix II (Following Code of Best Practice, ASX)

Study Title
CUV009. A Phase I Pharmacokinetics study of two doses 28 days apart.

Primary endpoints
a) Plasma CUV1647 concentration-time profile.

Secondary endpoints
a) Adverse events and changes in clinical measurements from baseline.
b) Changes in melanin density from baseline.

Blinding status
Open label.

Product Development Status
Good Manufacturing Practice (GMP) Standard.

Treatment method, frequency, dose levels
A single resorbable implant (16 mg CUV1647) administered subcutaneously and repeated 28 days later

Number of trial subjects
10 patients

Subject selection criteria
Healthy males, aged 18-45 years, with Fitzpatrick skin types I, II or III and no significant medical conditions or organ dysfunction.

Trial location
Single centre,
Centre for Pharmaceutical Research, School of Pharmacy and Medical Sciences,
University of South Australia, Adelaide.

Duration of the trial
84 days

Trial standard
In compliance with Good Clinical Practices (GCP) and ICH guidelines.

About Clinuvel Pharmaceuticals Limited

Clinuvel Pharmaceuticals Limited (ASX:CUV, XETRA:UR9, ADR:CLVLY) is an Australian biopharmaceutical company developing its photoprotective drug CUV1647 as a preventative treatment for a range of UV-related skin disorders as well as cancer related treatments.

The five indications are:

Indication	Description	Clinical Trial Status
Polymorphic Light Eruption (PLE / PMLE)	Severe sun poisoning	Phase III trials started May 2007
Erythropoietic Protoporphyria (EPP)	Absolute sun intolerance	Phase III trials started April 2007
Actinic Keratosis (AK) and Squamous Cell Carcinoma (SCC) in Organ Transplant Patients (OTP)	Precursor to skin cancer / non-melanoma skin cancer	Phase II trials started October 2007
Solar Urticaria (SU)	Acute anaphylactic reaction to sun	Phase II trials planned to begin 2nd quarter 2008
Phototoxicity associated with Photodynamic Therapy (PDT)	Photosensitivity associated with cancer treatment	Phase II trials planned to begin 1st half 2008

Phase I and II human clinical trials using CUV1647 have demonstrated that the drug is well tolerated and no significant safety concerns have been identified to date.

Following successful conclusion of the development program, Clinuvel will work closely with global regulators to apply for marketing approval of CUV1647.

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