

D-Pharm Ltd. invites Contract Research Organizations (CROs) to submit proposals for the execution of a Phase III acute stroke study with DP-b99. Proposals are expected by mid April 2008.

The compound:

DP-b99 is a membrane-activated ion chelator with demonstrable neuroprotective effects in animal and *in-vitro* models, and a favourable safety profile in healthy young and elderly human subjects as well as in stroke patients. In a recently completed Phase IIb study in acute stroke patients DP-b99 had a pronounced effect promoting recovery (see: http://www.esc-archive.eu/glasgow07/gla_so10_1.asp). DP-b99 is administered intravenously within 9 hours following stroke symptoms onset, and in the proposed study will be administered in total for 4 consecutive days.

The study:

This will be a double-blind, placebo controlled, randomized, multi-centre and multi-national, 2-arm study, with an interim efficacy analysis and ongoing safety monitoring by a DSMB. The study will not be imaging-based. The follow up period per patient will be 90 days. The study will be performed under IND, and its results may be submitted to various regulatory authorities as part of an application for marketing authorization.

The sample size:

The statistical planning of the study is currently underway. It is estimated that approximately 750 patients will be needed.

The population:

The target population of this study should be patients suffering an acute hemispheric non-hemorrhagic stroke (hemorrhage to be excluded by CT or MR scan at entry) of moderate severity with a clinical indication of cortical involvement.

Trial's territories:

It is estimated that about 130 centers will be required. Sites should be recruited primarily from the USA, Canada and Western Europe. However, other sites/countries will be considered acceptable as long as their standard of acute stroke care is compatible with US/Western European standards, and as long as the CRO has experience performing clinical studies in these countries.

The timeline:

Regulatory submissions are expected in Q4 2008. Total enrolment (LPI, assuming study continues after interim analysis) should be complete by Q1 2011.

The proposal:

The proposal should be of a full service package. In addition to discussing the common tasks involved in every study, from protocol writing through final integrated report writing, the CRO is expected to relate in detail in the proposal to the following issues:

- The CRO's past experience with acute stroke, or similar (e.g. acute traumatic brain injury), studies, including availability of experienced personnel for this study
- Experience with IVRS and electronic data capture systems in regulatory pivotal studies
- Potential need for additional sub-contractors (if known, please provide names of preferred options)

The proposal should also include a suggested scheme for study organization (including proposed key personnel), as well as cost estimates for the CRO's professional fees and anticipated pass-through expenses.



Kiryat Weizmann Science Park, Bldg.7
P.O. Box 2313, Rehovot 76123, Israel
Tel. 972-8-9385100
Fax. 972-8-9300795

CROs interested in submitting a proposal that wish to receive further information are kindly requested to:

(1) Complete and sign the attached Non-Disclosure Agreement and fax the signed agreement to the attention of Gilad Rosenberg, M.D., VP Clinical Development, D-Pharm Ltd., at fax number: 972 8 9300 795 (please provide a fax number to which a fully executed copy will be sent). Additionally, 2 copies of the originally signed agreement should be sent by mail to: Gilad Rosenberg, M.D., VP Clinical Development, D-Pharm Ltd., P.O. Box 2313, Rehovot 76123, Israel, of which one fully executed copy will be returned to the sender.

(2) Following the completion of (1), initiate contact by emailing grosenberg@dpharm.com



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NON-DISCLOSURE AGREEMENT

made as of this ____ day of _____, 20____.

D-Pharm Ltd., a company organized and existing under the laws of Israel (the “Transferor”) and _____ a company organized and existing under the laws of _____ (the “Recipient”) hereby agree as follows:-

1. All technical, commercial and financial information, whether communicated orally or in writing (including, but not limited to, documentation, drawings, designs, reports, surveys, formulae, questionnaires, correspondence, data, specifications, and/or the like), furnished and/or transferred by the Transferor to the Recipient in respect of Transferor’s proprietary MAC technology, DP-b99 and relevant derivatives (collectively the “Proprietary Data”), shall, save as otherwise provided in section 6 below, be deemed to be proprietary to the Transferor.
2. Any Proprietary Data previously provided to the Recipient or its representative or Affiliates (as defined herein) shall be subject to the requirements of this Agreement as fully as if this Agreement had been in effect on the date such information was provided.
3. The Recipient shall utilize the Proprietary Data solely for the purpose of determining its interest in cooperating with the Transferor, and for no other purpose whatsoever, until or unless a formal written contract is entered into providing the terms and conditions of use, and the rights to be acquired by the Recipient.
4. The Recipient agrees to retain the Proprietary Data in strict confidence and shall exert the same effort and shall take the same steps to avoid disclosure of the Proprietary Data as the Recipient employs with respect to its own confidential and proprietary information.
5. Recipient shall not, directly or indirectly, communicate, publish, describe, or divulge the Proprietary Data to others, except to the Recipient's employees who need to know to the extent necessary for the purposes hereof on the conditions set forth below :-
 - 5.1. Each authorized employee of the Recipient to whom any of the Proprietary Data is communicated will be informed that same is confidential and will agree not to disclose such Proprietary Data to others.
 - 5.2. Each authorized employee of the Recipient to whom any of the Proprietary Data is communicated will agree not to use any of same except for the purpose of considering the business relationship contemplated herein.
6. The restrictions set forth above shall not apply in respect of Proprietary Data and other documentation and/or information which:-
 - 6.1. at the time of disclosure, is in the public domain;
 - 6.2. after disclosure becomes a part of the public domain through no act or omission by the Recipient or any of its employees;

- 6.3. as shown by written records, was in the possession of the Recipient prior to disclosure by the Transferor; and
- 6.4. is rightfully received by the Recipient from third parties who were entitled to receive and transfer the Proprietary Data.

provided that the Recipient shall have immediately notified the Transferor in writing of any of the above conditions having been met.

7. Proprietary Data shall not be deemed to be within the exceptions of section 6, hereinabove, merely because:
 - 7.1. it is specific and embraced by more general information in the public domain or Recipient's possession, or;
 - 7.2. a combination can be pieced together to reconstruct the Proprietary Data from multiple sources, none of which shows the whole combination, its principle of operation and method of use.
8. The Proprietary Data is, and shall always remain, the exclusive property of the Transferor, and the Recipient hereby acknowledges the right, title and interest of the Transferor in and to the Proprietary Data. The Recipient will not at any time infringe, contest, dispute or question such right, title or interest nor aid others in doing so, directly or indirectly.
9. Nothing contained in this Agreement will be construed as creating an express or implied license to the Recipient to practice the Proprietary Data or as a commitment or an obligation on the part of the Transferor or the Recipient to enter into any future agreement relating to the Proprietary Data.
10. Any documents furnished by the Transferor to the Recipient containing Proprietary Data shall be promptly returned to the Transferor or destroyed upon the Transferor's request.
11. The terms of this Agreement shall be binding upon the Recipient as well as its respective "Affiliates" as hereinafter defined:-

"Affiliate" - any company which at the time of the execution of this Agreement and/or at any time throughout its validity is:

 - 11.1. a parent company of the Recipient; or
 - 11.2. a company in which the Recipient owns or controls directly or indirectly 50% (fifty percent) or more of the voting stocks.
12. The Recipient acknowledges and agrees that non-permitted disclosure of the Proprietary Data would irreparably damage the Transferor in such a way that the Transferor could not be adequately compensated in damages in an action at law. In consideration of this fact, the Recipient agrees that should any dispute arise concerning the disclosure or utilization of the Proprietary Data, an injunction may be issued, without bond, restraining such disclosure or use in contravention of this Agreement. Such remedy shall be cumulative and non-exclusive and shall be in addition to any other legal or equitable remedy to which the Transferor may be entitled.
13. This Agreement shall commence as of the date first above written and shall continue in full force and effect for a period of 5 (five) years.



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P.O. Box 2313, Rehovot 76123, Israel
Tel. 972-8-9385100
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14. Any and all notices and communications in connection with this Agreement shall be addressed to the parties as follows:

TRANSFEROR

RECIPIENT

D-Pharm Ltd.
Kiryat Weizman Science Park
P.O.Box 2313, Rehovot 76123
Israel
Fax: + 972-8-9300795
Attn: Dr. Alexander Kozak

Fax:
Attn:

All notices shall be given by facsimile, by registered mail, or by manual delivery in the English language, to the parties respective addresses as above or such other address as may be designated by notice. All facsimile notices shall be deemed received within 24 (twenty-four) working hours from the dispatch thereof, while all registered mail notices shall be deemed received within 5 (five) calendar working days of the dispatch thereof.

15. It is understood and agreed that no failure or delay by the Transferor in exercising any right, power or privilege under this Agreement shall operate as a waiver thereof or preclude any other right, power or privilege hereunder. This Agreement shall be binding upon the parties and their successors.
16. This Agreement contains the entire understanding between the parties with respect to the matters contemplated herein and supersedes all previous written and oral negotiations, commitments and understandings. This Agreement cannot be altered or otherwise amended except pursuant to an instrument in writing signed by each of the parties hereto and making specific reference to this Agreement.
17. This Agreement shall be governed by, and construed in accordance with the laws of the State of Israel.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

TRANSFEROR

RECIPIENT

By: _____

By: _____