

Edgar Filing: INFINITY PHARMACEUTICALS INC - Form 425

INFINITY PHARMACEUTICALS INC

Form 425

August 17, 2006

Filed by Discovery Partners International, Inc. Pursuant to Rule 425

Under the Securities Act of 1933

and Deemed Filed Pursuant to Rule 14a-12

Under the Securities Exchange Act of 1934

Subject Company: Infinity Pharmaceuticals, Inc.

Commission File No. 333-134438

**Additional Information about the Merger and Where to Find It**

In connection with the proposed merger transaction between Infinity Pharmaceuticals, Inc. ( Infinity ) and Discovery Partners International, Inc. ( Discovery Partners ), on August 7, 2006, Discovery Partners filed with the Securities and Exchange Commission (the SEC ) an amended registration statement that contains a proxy statement/prospectus, which registration statement has been declared effective by the Securities and Exchange Commission. Investors and securityholders of Discovery Partners and Infinity are urged to read the proxy statement/prospectus (including any amendments or supplements to the proxy statement/prospectus) regarding the proposed transaction because it contains important information about Discovery Partners, Infinity and the proposed transaction. Discovery Partners stockholders can obtain a free copy of the proxy statement/prospectus, as well as other filings containing information about Discovery Partners and Infinity, without charge, at the SEC s Internet site (<http://www.sec.gov>). Copies of the proxy statement/prospectus can also be obtained, without charge, by directing a request to Discovery Partners International, Inc., 9640 Towne Centre Drive, San Diego, CA 92121, Attention: Investor Relations, Telephone: (858) 455-8600.

**Participants in the Solicitation**

Discovery Partners and its directors and executive officers and Infinity and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Discovery Partners in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the merger transaction is included in the proxy statement/prospectus referred to above. Additional information regarding the directors and executive officers of Discovery Partners is also included in Discovery Partners proxy statement for its 2006 Annual Meeting of Stockholders, which was filed with the SEC on April 6, 2006. This document is available free of charge at the SEC s web site (<http://www.sec.gov>) and from Discovery Partners Investor Relations at the address listed above.

On August 16, 2006, Infinity made the presentation set forth below to a limited group of investors.

Introduction to Infinity  
August 16, 2006

## Forward-Looking Statements

Various statements in this presentation concerning our future expectations, plans and prospects constitute forward-looking statements for the purposes of the safe harbor provisions under The

Private

Securities

Litigation

Reform

Act

of

1995.

Such

forward-looking

statements

include

statements regarding the proposed transaction with Discovery Partner International (DPI), DPI

and

the

combined

company's

net

cash

at

closing,

anticipated

cash

post-closing

and

projected period in which such cash will be available, the trading of the combined company's

shares on the

NASDAQ

National

Market,

the

potential

value

created

by

the

proposed

merger

for

DPI's

and Infinity's stockholders, the efficacy, safety, and intended utilization of

Infinity's product candidates, the results of discovery efforts and clinical trials, and plans regarding regulatory filings, future research and clinical trials and current and future collaborative activities. Actual results may differ materially from those indicated by such forward-looking statement as a result of various important factors, including risks related to: the ability of DPI and Infinity to complete the proposed transaction; the amount of DPI's net cash at closing; the availability of funds to continue research and development activities; the results of future clinical trials with respect to Infinity's product candidates and compounds and Infinity's ability to successfully develop and commercialize product candidates; the success of Infinity's collaborations and its ability to enter into additional collaborations;; the timing and success of regulatory filings;; the scope of Infinity's patents and the patents of others; competitive factors and other risks and

uncertainties  
more  
fully  
described  
in  
DPI's  
filings  
with  
the  
Securities  
and  
Exchange  
Commission,  
including  
its  
Registration  
Statement  
on  
Form  
S-4,  
as  
filed  
on  
May  
24,  
2006  
and  
subsequently  
amended.  
The  
proposed  
transaction  
is  
subject  
to  
customary  
closing  
conditions,  
including  
approval  
of  
DPI's  
and  
Infinity's  
stock  
holders.

Any forward-looking statements speak only as of the date made. Infinity undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Mission

To develop targeted therapies for the treatment of cancer and related conditions discovered through the use of our innovative small molecule drug technologies

Lead product candidate: IPI-504, a novel Hsp90 inhibitor

Two ongoing Phase I cancer studies in GIST and multiple myeloma

Phase II expected 2007

Pipeline of preclinical cancer drug candidates

Internally discovered and developed, chemistry platform

4 Pharma/Biotech corporate alliances

Amgen, J & J and Novartis (2)

Proven biotech leadership team

Expected cash runway post-DPI merger

~ \$90+ million

Sufficient funds through 2007

Infinity Snapshot

Strategy

Drugs

Internally discovered, novel small molecules

Targets

Well-credentialed, but not well-trodden

Products

Opportunity for first-in class or fast follower best-in-class



## Overview

Founded in late 2001 (~5 years old)

## Team

Recognized biotechnology investor, business and R&D leaders

~115 employees (~55 PhD / MDs)

## Alliance and Financing Strategy

Small molecule technology access alliances with Amgen, J&J and Novartis

Bcl-2 product alliance with Novartis

Public financing via Reverse Merger with Discovery Partners

IPI-504

lead proprietary oncology drug candidate (Hsp90)

Phase I in GIST and multiple myeloma commenced 2005

Phase II anticipated in 2007

Hedgehog pathway  
preclinical oncology candidate

Our Team: ~115 full-time employees

Infinity headcount

Biology/Clinical/Regulatory

36

Chemistry

50

Management & other

12

(~55 MD or PhDs)

R&D Total

98

Total

115

G&A

17

Well-balanced

Moderate near-term growth

anticipated

Primarily in downstream  
disciplines (i.e. clinical,  
regulatory, CMC/ADME/tox)

Leadership

Mr. Steven Holtzman, CEO

Millennium, DNX

Dr. Julian Adams, President & CSO

Millennium, ProScript

Boehringer

Ingelheim, Merck

Ms. Adelene Perkins, CBO

Transform, Genetics Institute,

Bain, GE

Dr. Michael Foley, VP Chemistry

Harvard ICCB, Glaxo, BMS

Dr. David Grayzel, VP Clinical Development  
& Medical Affairs

Dyax, Mass General Hospital

Dr. Vito Palombella, VP Discovery Biology

Syntonix, Millennium, ProScript

Dr. Jeffrey Tong, VP Corp & Prod Dev

McKinsey & Co, Harvard Center for  
Genomics Research

Dr. Jim Wright, VP Pharm

Dev

Millennium, Alkermes, Boehringer

Ingelheim, Syntex, U. of Wisconsin

SAB  
Oncology & Chemistry

Co-chair: Stuart Schreiber, PhD -  
Co-Director Broad Institute, Prof. of Chemistry and  
Chemical Biology Harvard University

Co-chair: Rick Klausner, MD  
Column Group, former Head of the NCI

Arnie  
Levine, PhD -  
Institute for Advanced Study

Eric Lander, PhD -  
Co-Director Broad Institute, Whitehead, MIT, Harvard

Todd Golub, MD -  
DFCI, Broad Institute, Harvard, MIT

David Livingston, MD  
Professor of Medicine, Harvard Medical School, DFCI

Ken Anderson, MD -  
Robert Kraft Prof. of Medicine Harvard Medical School, DFCI

Matthew Shair, PhD  
Professor of Chemistry, Harvard University

Vicki Sato, PhD  
former President Vertex Pharmaceuticals

Phil Needleman, PhD -  
former Head of R&D Searle, Pharmacia

Investors  
Venture Capitalists

Prospect Venture Partners

Venrock Associates

Advent Venture Partners

HBM BioVentures

Vulcan Ventures

Novartis BioVentures

Wellcome  
Trust

POSCO BioVentures

Tallwood

Alexandria Equities

Lotus BioScience  
Pharmaceutical Companies

Amgen

Novartis

J&J

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Phase II anticipated in 2007



Hedgehog pathway  
preclinical oncology candidate

DOS Small Molecule Technology: Discovery and Alliance Engine

Innovative small molecule platform, diversity oriented synthesis (DOS), enables the creation of novel, natural product-like synthetic drug candidates

Potential  
to  
access  
previously  
undruggable  
drug  
targets

Unique asset for:

Internal drug discovery

Value-accretive technology access alliances

N  
O  
O  
H  
R<sup>2</sup>  
R<sup>3</sup>  
N  
O  
R<sup>3</sup>  
H  
H  
H  
O  
O

N  
R  
4  
O  
R  
R<sub>2</sub>  
R<sub>1</sub>  
N  
O  
NR  
4  
O  
R<sub>1</sub>  
O  
SR<sub>2</sub>  
R<sub>3</sub>

Diversity Oriented Synthesis (DOS)

2004

2006: > \$65 million upfront/committed cash

Additional milestone and royalty potential

No license of proprietary Infinity product rights

Small Molecule Technology Access Alliances

Total payments >\$400M  
Early product pipeline: Bcl-2 alliance with Novartis

Joint discovery of novel Bcl-2  
targeted cancer drugs

Infinity participation in clinical  
development (at NVS expense)  
COLLABORATION

Infinity participation in US sales  
effort (at NVS expense)  
\$30M

Upfront &

committed funds  
FINANCIALS

Royalties on WW sales

Discovery  
Preclinical  
Start Clinical  
Trials  
Hsp90  
(IPI-504)  
Bcl2/Bcl-xL  
2005  
2007/2008\*  
100% owned  
100% owned  
Novartis  
Non-exclusive

Amgen

Novartis

J&J  
Small molecule drug technologies

Alliance and financing strategy: value retention

Hedgehog

Pathway

(IPI-609)

2007\*

\*Planned



Reverse Merger  
with  
Discovery Partners International, Inc.  
(NASDAQ: DPII)

\*\*\*\*\*  
\*\*\*\*\*  
\*\*\*\*\*

DPI reverse merger opportunity

Discovery Partners International

Publicly traded company on NASDAQ (DPII)

Cash position 1/1/06: > \$83M

Board mandate (Q1, 2006):

Shut down existing business

Seek alternative, high-value biotech investment opportunity

DPI undertakes extensive evaluation of merger candidates

DPI selects Infinity as preferred partner

A financing event only

NO

programs, employees, partnerships,  
or obligations of DPI transferred to Infinity

DPI invests

cash and divests operating units

7/7/06: Sale of all DPI operating assets to Galapagos

If DPI cash between \$70M and \$75M, ownership:

DPII stockholders = 31%

Infinity stockholders = 69%

If cash above \$75M or below \$70M, adjustment applied

Expected reverse stock split at closing to lower share number and  
increase share price

The reverse merger: a creative financing and access to  
public markets

Lead clinical product in two ongoing Phase I cancer studies

Phase II expected 2007

Pipeline of preclinical cancer drug candidates

Internally discovered and developed, chemistry platform

4 Pharma/Biotech corporate alliances

Amgen, J & J and Novartis (2)

Proven biotech leadership team

Estimated approximately \$90 million cash

Projected cash runway through 2007 and key value driving events  
before any additional alliances or financing

Snapshot of Post-Merger Infinity (NASDAQ: INFI)

Status of Reverse Merger

Announce merger

File Initial S4

S-4 is Declared Effective

S-4 mailed to DPI and IPI Stockholders

Stockholder meeting/vote scheduled

Deal Closes, INFI publicly traded

April 12, 2006

July 11, 2006

August 7, 2006

August 9-10, 2006

September 12, 2006

Following successful vote

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Phase I in GIST and multiple myeloma commenced 2005

Phase II anticipated in 2007

## Hedgehog pathway

preclinical oncology candidate

Novel Hsp90 inhibitor

Currently in 2 Phase I clinical trials:

GIST

Multiple myeloma

Ready for Phase II in 2007

Both IV (water-soluble) and oral  
formulations

Infinity's lead clinical product: IPI-504 (Hsp90 inhibitor)

Cl

-

IPI-504

OH

N

H

N  
OH  
O  
OH  
Me  
O  
O  
O  
O  
NH  
2  
H  
H  
+



Heat Shock Protein 90 (Hsp90) is an emerging cancer target

Hsp90 in cancer cells differs from

Hsp90 in normal cells\*

Function of Hsp90 in cancer cells

General chaperone function

essential for protein homeostasis

Specific chaperone function

stabilization of oncogenic proteins in key cell signaling pathways

Preferential targeting to cancer

\*Reference: Kamal  
et al, Nature,  
2003, 425,.407-410

Dependence  
on Hsp90  
Apoptosis  
Tyrosine kinase  
inhibitor  
(e.g  
Gleevec, Tarceva)  
Oncogene  
Cancer cell  
survival &  
proliferation  
Resistance  
mutations  
Hsp90  
inhibitor  
Targeting specific oncogenic Hsp90 client proteins  
Hsp90  
inhibitor

Velcade  
Gleevec / dasatinib  
Investigational  
Gleevec / Sutent  
Herceptin  
Tarceva  
/ Erbitux  
Sorafenib  
/ Sutent  
Sorafenib  
Investigational  
Targeted therapy  
The emerging world of targeted cancer therapies  
Indication  
Myeloma  
CML  
AML  
GIST

Breast (HER2+)  
NSCLC  
Renal cell  
Melanoma  
Prostate (PTEN -/-)  
NF-  
B  
Bcr-Abl  
Flt3  
c-Kit  
HER2  
EGFR  
VEGFR / HIF-1a  
b-Raf  
p-Akt  
Molecular Target

The emerging world of targeted cancer therapies

NF-

B

Bcr-Abl

Flt3

c-Kit

HER2

EGFR

VEGFR / HIF-1a

b-Raf

p-Akt

Molecular Target

All are clients of Hsp90

Inhibiting Hsp90 affects the  
stability of these targets

History of Geldanamycin analogs

17-AAG is a semi-synthetic natural product, derived from Geldanamycin

17-AAG activity:

Potent & selective inhibitor of Hsp90

Well-tolerated in humans (>400 patients tested in multiple Phase I trials)

Removed chemical reactivity of geldanamycin

Problems:

Highly insoluble

Sub-optimal DMSO-and  
Cremophor  
based formulations

Off-patent

O

N

H

H

N

O

Me

O

OH

Me

Me

O

Me

O

O

O

N

H

Me

Me

17-AAG



Novel chemical entity

Patient-friendly formulations

IV in two Phase I trials

Oral under development

Broad therapeutic potential

Strong intellectual property position

Phase II planned for 2007

CI

-

Infinity's lead clinical product: IPI-504 (HSP90 inhibitor)

IPI-504

OH

N

H  
N  
OH  
O  
OH  
Me  
O  
O  
O  
O  
NH  
2  
H  
H  
+

IPI-504

IPI-504 competitive landscape for IV formulation

POTENCY

DELIVERY

CHEMICAL

PROPERTIES

MTD

COMPOUND

COMPANY

17-DMAG

KOS-1022

~25-50 nM

IV 60 120

min  
Chemically  
reactive  
alkylating  
agent  
<24 mg/m<sup>2</sup>  
Kosan  
17-AAG  
KOS-953  
~25-50 nM  
IV 60-120 min  
in Cremophor  
Special tubing  
Steroid  
pretreatment  
Emulsion  
changes  
distribution  
and PK  
Dose escalation  
ongoing;  
>  
340 mg/m<sup>2</sup>  
Kosan  
Emulsion  
changes  
distribution  
and PK  
17-AAG  
CNF-1010  
~25-50 nM  
IV 60 min  
in lipid  
emulsion  
175 mg/m<sup>2</sup>  
Biogen/  
Conforma  
Emulsion  
changes  
distribution  
and PK  
17-AAG  
~25-50 nM  
IV 60 min in  
DMSO/Egg  
220 mg/m<sup>2</sup>  
Kosan  
IPI-504  
~25-50 nM  
IV 30 min

Diffusion  
controlled  
distribution  
Dose escalation  
ongoing at  
400 mg/m<sup>2</sup>  
Infinity

IPI-504 competitive landscape for PO formulations

IPI-504 (same  
molecule as IV)

17-DMAG

CNF-2024

Small Molecule

Small Molecule

Small Molecule

Compound

Company

Phase of Development

Infinity

Kosan

Biogen

Idec

Serenex

Novartis /  
Vernalis  
Synta  
Pre-clinical  
Phase I  
Phase I  
Preclinical  
Preclinical  
Preclinical  
Novel small  
molecules not  
derived from  
geldanamycin



Intellectual property protection for IPI-504

Composition of matter

Formulations (IV and PO)

Methods of making

Methods of using

Infinity has broad patent applications pending for IPI-504

IPI-504 Preclinical Data

\*  
\*  
\*  
\*  
\*

Highly  
responsive to  
Hsp90 inhibition  
T315I  
T790M  
T670I  
Preclinical evidence of potential as salvage therapy  
BCR-ABL  
EGFR  
KIT  
Hsp90 Client  
Disease  
Drug  
CML  
NSCLC  
GIST  
Gleevec,  
Dasatinib  
Tarceva,  
Iressa  
Gleevec,

Sutant  
Kinase  
Inhibitor  
Resistance  
Mutation

CML / Bcr-Abl  
Wild-type protein  
Bcr  
Abl  
Non-cancer related  
Protein status  
Entity  
Function  
Hsp90-  
dependent  
Gain-of-function  
mutant  
Bcr-Abl  
fusion  
Constitutively  
activated signaling  
Drug-resistant  
mutant  
Bcr-Abl  
(T315I)

TKI-resistant  
kinase

Gleevec-refractory primary CML cells sensitive to IPI-504

0

10

20

30

40

50

60

70

Pt 1

Pt 2 (T315I)

Pt 3

Control

0.5 uM IPI-504

2.0 uM IPI-504

Collaboration:

Kapil Bhalla, Moffitt Cancer Center

Placebo  
Gleevec  
IPI-504  
0.0%  
20.0%  
40.0%  
60.0%  
80.0%  
100.0%  
15  
17  
19  
21  
23  
25  
27  
29



31

33

Days

Oral IPI-504: survival benefit in Gleevec-resistant T315I

CML transplantation model

Collaboration: Shauguang

Li, Jackson Labs

Gleevec

2x daily, 100 mg/kg

IPI-504 oral MWF, 100 mg/kg ( $p=0.001$ )

Placebo  
Gleevec  
IPI-504  
0.0%  
20.0%  
40.0%  
60.0%  
80.0%  
100.0%  
15  
17  
19  
21  
23  
25  
27  
29

31

33

Days

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CML transplantation model

Collaboration: Shauguang

Li, Jackson Labs

Gleevec

2x daily, 100 mg/kg

IPI-504 oral MWF, 100 mg/kg ( $p=0.001$ )

Placebo  
Gleevec  
IPI-504  
0.0%  
20.0%  
40.0%  
60.0%  
80.0%  
100.0%  
15  
17  
19  
21  
23  
25  
27  
29

31

33

Days

Oral IPI-504: survival benefit in Gleevec-resistant T315I

CML transplantation model

Collaboration: Shauguang

Li, Jackson Labs

Gleevec

2x daily, 100 mg/kg

IPI-504 oral MWF, 100 mg/kg ( $p=0.001$ )

NSCLC / EGFR  
Wild-type protein  
EGFR  
Ligand-dependent  
RTK  
Protein status  
Entity  
Function  
Hsp90-  
dependent  
Gain-of-function  
mutant  
EGFR  
(  
exon19 or  
L858R)  
Ligand-  
hypersensitive RTK  
Drug-resistant  
mutant

EGFR  
(  
exon19 or  
L858R + T790M)  
TKI-resistant,  
ligand  
hypersensitive RTK

0  
500  
1000  
1500  
2000  
2500  
3000  
3500  
4000  
12  
15  
19  
22  
26  
27  
32



Days Post-Implant  
IPI-504 Vehicle, IP  
Gefitinib Vehicle, PO  
100mpk Gefitinib, PO  
100mpk IPI-504, IP

100mpk  
IPI-504  
2X  
weekly  
IP;  
100mpk  
Gefitinib  
daily  
PO  
for  
3  
weeks

21%  
difference  
in  
tumor  
volumes  
between  
vehicle  
and  
Gefitinib  
treated  
groups  
( $p=0.54$ )

69% difference in tumor volumes between vehicle and IPI-504 treated groups ( $p=0.009$ )

69%  
Non small cell lung cancer xenograft with T790M EGFR  
Tarceva/Iressa-resistance mutation

GIST / Kit  
Wild-type protein  
Kit  
Ligand-dependent  
RTK  
Protein status  
Entity  
Function  
Hsp90-  
dependent  
Gain-of-function  
mutant  
c-Kit  
Ligand-independent  
RTK  
Drug-resistant  
mutant  
c-Kit (T670I)  
TKI-resistant,  
ligand-independent

RTK

GIST: Gleevec-resistant cells more sensitive to IPI-504

GIST 882\*

Gleevec-Sensitive

(primary: exon

13, K642E)

10

100

1000

10

20

30

40

50

10000

60

70

Compounds concentrations (nM)

10

100

1000

10  
20  
30  
40  
50

10000  
10000

60  
70

Compounds concentrations (nM)

IPI-504 : EC50 = 121 +/-

21 nM

IM : EC50 = 147 +/-

42 nM

Gleevec-

Resistant

(primary: exon

11, V560D +

Gleevec resistance: exon

17, D820A)

10

100

1000

5

15

25

35

45

55

65

75

85

Compounds concentrations (nM)

IPI-504

Imatinib

GIST 48\*

IPI-504 : EC50 = 54 +/-

7 nM

IM : 25% inhibition @ 10uM

Collaboration:

Fletcher, Demetri, DFCI

IPI-504 Clinical Development Strategy

- \*
- \*
- \*
- \*

Development and registration of IPI-504 in hematologic malignancies and solid tumors

Preclinical support for broad role of Hsp90

Early human proof-of-concept with rapid path to registration

Strong scientific rationale

Trials targeted to homogenous patient population (disease-focused)

Surrogate marker

Rapid patient accrual

Single-agent activity in refractory setting (potential for expedited approval)

In parallel, initiate broader development for larger indications (additional diseases, combination therapy, front-line therapy)  
IPI-504 Clinical Development Strategy

Principal Investigator:

Dr. George Demetri, DFCI

Objectives:

Safety, PK, dose-ranging

Establish Phase II dose

Surrogate marker of response:

PET scans

Solid Tumor

Gastrointestinal Stromal Tumors

(Gleevec-resistant)



Schedule / status:

Days 1, 4, 8, 11 of 21 day

Continuing dose escalation

Current ongoing phase I clinical trials

Principal Investigator:

Dr. Paul Richardson, DFCI

Dr. Sundar Jagannath, SVCCC

Dr. David Siegel, HUMED

Objectives:

Safety, PK, dose-ranging

Establish Phase II dose

Surrogate marker of response:

M protein levels

Hematologic

Multiple Myeloma

(relapsed, refractory)

Schedule / status:

Days 1, 4, 8, 11 of 21 day

Continuing dose escalation

Phase I dose escalation for IPI-504 (GIST)

1 cycle = 21 days

4 doses (days 1, 4, 8, 11 followed by 10 days off)

Phase I schedule

25%

500

6

33%

400

5

33%

300

4

50%

225  
3  
66%  
150  
2  
100%  
90  
1  
Escalation over  
previous dose  
Dose (mg/m<sup>2</sup>)  
Group

Near-term sequence of additional clinical indications  
(2006/2007)

Resistance

Mutation

Disease

PI

T. Lynch

T. Kipp, CLL

consortium

Matsui, Smith /

Bhalla

NSCLC

CLL

CML

Tarceva-R

(T790M )

Zap-70

T315I

Focused trials would determine IPI-504 activity in patients with known resistance to targeted therapy

If positive, trials provide opportunity to rapidly advance to market

Additional indications to follow

Site

MGH

UCSD

JHU, Moffitt

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Bcl-2 product alliance with Novartis

Public financing via Reverse Merger with Discovery Partners

## IPI-504

lead proprietary oncology drug candidate (Hsp90)

Phase I in GIST and multiple myeloma commenced 2005

Phase II anticipated in 2007

## Hedgehog pathway

preclinical oncology candidate

Potential for first-in-class systemic hedgehog inhibitor

Proprietary NCE s

Systemic (sub-cu and oral) products

Lead molecule (IPI-609) in advanced preclinical development

First in man expected in 2007

Broad anti-cancer potential

Strong data supporting pancreatic, metastatic prostate, SCLC, others

Single agent activity

Potential for synergy with standards of care  
Infinity s Hedgehog program

History of cyclophamide  
chemical discovery  
1950 s

Lambs born in Idaho with cyclopic  
features (defect in development of  
left-right asymmetry)

USDA determines that pregnant  
ewes grazed on the plant *Veratrum*  
*californicum*

Cyclophamide  
identified as the  
teratogenic substance in *V.*  
*californicum*



Purified cyclopamine given to  
animals recapitulates cyclopic  
features and other birth defects  
*V. californicum*  
cyclopamine

History of hedgehog  
genetics  
40 years later (1980 s to today)

Genes are discovered that control  
embryonic development and pattern  
formation

One such gene is called hedgehog

Hedgehog mutations in the Drosophila  
fruit fly result in cyclopia

Hedgehog function in humans related  
to development of the pancreas, gut,

and other elements of GI tract

Cyclopamine chemistry meets hedgehog genetics

Chemistry

The chemical cyclopamine  
results in cyclopic animals

Genetics

Mutation of hedgehog pathway  
results in cyclopic animals

Might the chemical cyclopamine interact  
with genes in the hedgehog pathway?

YES

Cyclopamine is a smoothed antagonist

\*Chen et al., 2002 **G&D**

16:2743

Cyclopamine

Normal

Cancer

Cancers have hijacked components of the hedgehog pathway

#

ON = active repressor of Smo

\* Mutation in Patched

1

Hahn *et al.*, 1996, **Cell**

85: 841

2

Bale & Yu, 2001, **Human Molec. Genetic.** 10: 757 (review)

3

Berman *et al.*, 2002 **Science**

297: 1559

4

Berman *et al.*, 2003 **Nature**

425: 846

5

Kayed *et al.*, 2004 **Int. J. Cancer**

110: 668

6

Thayer *et al.*, 2003 **Nature**

425: 851

7

Karhadkar *et al.*, 2004 **Nature**, 431: 707

8

Fan *et al.*, 2004 **Endocrinology**

145: 3961

9

Watkins *et al.*, 2003, **Nature**

422: 313

10

Sicklick 2005 **ASCO**; Mohini, 2005 **AACR**

11

Kubo *et al.*, 2004 **Cancer Res.** 64

:6071

State

Normal

Basal cell carcinoma\*

1,2

Medulloblastoma\*<sup>3</sup>

Pancreatic cancer

4,5,6

Prostate cancer

7,8

Small cell lung cancer

9

Hepatocellular cancer

10

Breast Cancer

11

Smoothened

OFF

ON

ON

ON

ON

ON

ON

ON

Patched

#

ON

Mutant -

OFF

Mutant -

OFF

OFF

OFF

OFF

OFF

OFF

Hedgehog

OFF

OFF

OFF

Turned ON

Turned ON

Turned ON

Turned ON

Turned ON

Frequency

---

95%

30-40%

100%

100%

50%

n/a

100%



Cyclopamine validates Hedgehog as a cancer target

Cyclopamine is a plant natural product produced by *Veratrum californicum*

Cyclopamine activity:

Potent inhibitor of Smoothed

Highly active in pancreatic, prostate, small cell lung cancer animal models

Drawbacks:

Insoluble

Caustic formulations

Off-patent

HO

O

HN

H

H

H

H

H

Infinity's lead Hedgehog pathway inhibitors

Novel candidates based on cyclopamine

On mechanism

Superior to cyclopamine:

More chemically stable

More potent

More soluble

Most advanced candidate (IPI-609) in late-preclinical development

First in man 2007

i.v., s.c., or oral formulations

Better oral bioavailability

Better tumor PK

IPI-609 competitive landscape

CUR-61414

Curis

and Genentech Hedgehog antagonist

Highly insoluble: not suitable for systemic administration

Topical formulation failed in Phase 1 Basal Cell Carcinoma trial; failure attributed to formulation, not pathway

Curis

and Genentech

have expressed continued interest in the Hedgehog pathway for systemic agents

Intellectual property protection for IPI-609

Novel scaffold for IPI-609 and analogs with patent applications pending

We believe there are no patents preventing us from marketing IPI-609 or its analogs

0  
200  
400  
600  
800  
1000  
1200  
1400  
1600  
31  
36  
41  
46  
51  
56  
61

Days

Vehicle

IPI-609 10 mpk/day

IPI-609 efficacious in PC-3 prostate xenograft

IPI-609 slows tumor growth rates

0  
200  
400  
600  
800  
1000  
1200  
30  
35  
40  
45  
50  
55  
60

Day

Linear Fit

Bivariate Fit of P 10 By Day



200  
400  
600  
800  
1000  
1200  
30  
35  
40  
45  
50  
55  
60  
Day  
Linear Fit  
Bivariate Fit of VP 6 By Day  
Median vehicle-treated  
animals  
Median IPI-609 treated  
animals

Clinical development strategy of hedgehog pathway inhibitors

Strong scientific rationale supports targeting of cancers dependent on the Hedgehog pathway

Pancreatic

Small cell lung

Metastatic prostate

Metastatic breast

Ovarian

Others (medulloblastoma, glioma, basal cell carcinoma, etc.)

Identify a rapid path to registration

Potential for sole agent activity or

Combination with a single Standard of Care

Key Principal Investigator relationships established

Pancreatic cancer

Manuel Hidalgo, MD Johns Hopkins

(PCRT

Dan Van Hoff, MD)

Small cell lung cancer

Charles Rudin, MD Johns Hopkins

Prostate cancer

Phil Kantoff, MD DFCI

Howard Scher, MD MSKCC

Chris Logothetis, MD MD

Anderson

Prostate Consortium

Breast

Max Wicha, MD U of Michigan

Heme malignancies

Doug Smith, MD Johns Hopkins  
Bill Matsui, MD Johns Hopkins  
Kapil Bhalla, MD Moffitt Cancer Ctr

Infinity Pharmaceuticals  
Summary

\*  
\*  
\*  
\*  
\*  
\*

Product Pipeline

IPI-504: Complete Phase I trials

Publish First Clinical Data

IPI-504: Expect to initiate Phase II in 2007

Hedgehog Pathway: Expect to initiate  
Phase I in 2007

Successful alliance execution (Novartis, J&J, Amgen)

At least one new corporate alliance

Financing event

Year-end  
cash

runway:

12-24

months

2006/Early 2007 Goals, Achievements and Anticipated News Flow

NVS -

Bcl

Pending

DPII merger

AMGN

extension

Expected  
at EORTC  
11/7/06