

INSMED INC
Form FWP
September 28, 2012

Developing Innovative Inhaled Treatments for Serious
Lung Infections
August 2012
Free Writing Prospectus
Registration Statement No. 333-182124

This presentation contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this presentation, including statements relating to our financial position, projected year end cash and cash runway, the status and the results of preclinical studies and clinical trials and preclinical and clinical data described herein, the timing of responses to information and data requests from FDA, the development of our products, our estimates of the size of the potential markets for our product candidates, and the business strategies, evaluations, plans and objectives of management, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-

looking
statements.

Our
results
may
be
affected
by
such
factors
as
the
receipt
and
timing
of
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and
other

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December

31,

2011

and

our

Quarterly

Report

on

Form

10-Q

for

the

quarter

ended

June

30,

2012.

Investors

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Safe Harbor Statement

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Insmmed: Value Proposition

Attractive

Late-Stage

Opportunity

ARIKACE has strong Phase 2 efficacy and safety data in CF

Amikacin is an FDA-approved antibiotic, long recognized as one of the most effective treatments for gram-negative infections

Compelling

Business Model

Two orphan indications with high unmet need and combined global market potential of over \$1 billion

Limited commercial infrastructure required

Strong IP and potential for extended exclusivity

Strong Balance

Sheet &

Experienced

Management

As of 6/30/12, company reported ~\$75 million in cash, investments & CD

We believe cash is sufficient to take Company through the availability of top-line data for both CF CLEAR-108 trial and TARGET-NTM trial

Management has extensive anti-infective development, regulatory, and commercial experience

ARIKACE

®

* is a highly differentiated product that offers a compelling business opportunity in two orphan diseases

* ARIKACE

®

is a registered trademark of Insmmed Incorporated

ARIKACE (liposomal amikacin for inhalation), is in Phase 3 (CLEAR-108)

for cystic fibrosis (CF) *Pseudomonas (Pa)* lung infections and Phase 2

(TARGET-NTM) for non-TB mycobacteria (NTM) lung infections

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ARIKACE: Amikacin Summary

Amikacin is an FDA-approved antibiotic with proven efficacy in the treatment of gram-negative infections, including Pseudomonas and NTM

Aminoglycoside antibiotic

Value of the IV use has been limited

by nephro-toxicity and ototoxicity

ARIKACE (liposomal amikacin for inhalation) delivers high, sustained levels of drug to

the lung while reducing systemic exposure to well below established toxicity levels

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ARIKACE: Proprietary Liposomal Formulation Provides Basis
for Important Potential Benefits

Potential Benefit

Lipid Polar Head Groups

(at Both Surfaces)

Lipid Hydrophobic Chains

(Bi-Layer Interior)

Water Core (where Amikacin resides)

ARIKACE delivers the potency of Amikacin at the site of the lung infection;

engineered specifically for improved PK-PD* profile in the lung providing for potential enhanced efficacy, safety and convenience benefits

Greater efficacy by reaching infection site

Greater efficacy by reaching infection site

Greater efficacy and once-a-day dosing

Reduces potential for systemic toxicity

Engineered Specifically for Lung Delivery

Prolonged lung residence time

Biofilm penetration

Preferential uptake into macrophages

Minimal systemic exposure

* Pharmacokinetic-Pharmacodynamic (PK-PD)

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ARIKACE: Delivery Using Proprietary eFlow

®

Technology

ARIKACE is delivered once daily via the state-of-the-art PARI Optimized, Investigational eFlow Nebulizer System with Advanced Mesh Technology

Fast

drug delivery with efficient

lung deposition
Small, portable, silent and
cordless
device weighs less than
10 ounces.
eFlow Technology Device
exclusivity
from PARI Pharma for
15 years after first commercial
sale of ARIKACE

* eFlow

®

is a registered trademark of PARI Pharma GmbH

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ARIKACE: Development Plan

Target-NTM

Study in U.S.

ARIKACE vs. placebo in recalcitrant patients who are on a stable ATS/IDSA

guidelines-based

multi-drug

treatment

regimen;
N
100
No
inhaled
antibiotics
approved
for
treating
NTM
lung
infections
and
little
known competitive activity in clinic
Study
initiated
in
May-2012
top-line
results
from
randomized
portion
of
trial projected in 4Q13
CLEAR-109
CF Pseudomonas
Study for U.S.
FDA
removed
the
clinical
hold
for
CF
Pa
Phase
3
study
in
May
Insmmed
will
defer
plans
to
initiate
a
Phase

3

study

of

ARIKACE

in

the

U.S.

for

CF patients until the Company reviews top-line results from CLEAR-108

Insmed is focusing on CLEAR-108 (CF Pa Phase 3 Study) and TARGET-NTM

(NTM Phase 2 Study)

CLEAR-108

CF Pseudomonas

Study for

EU/Canada

ARIKACE

vs.

Tobi

®

(inhaled

tobramycin

solution);

N

300

Builds off of strong Phase 2 efficacy and safety data

Broad population with preferred trial design

Trial

initiated

in

April

2012

top-line

results

projected

in

mid-2013

Eligible

patients

roll-over

into

open-label

ARIKACE®

long

term

safety

and

tolerability study, CLEAR-110

* Tobi

®

is a Registered Trademark of Novartis Pharmaceuticals Corporation

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Arikace Cystic Fibrosis

Epidemiology and Disease Description

Cystic fibrosis is a life-threatening disease with significant unmet needs

Affects about 70,000 children

and adults worldwide (30,000 in

U.S. and Europe, each)

Inherited disease that causes

thick, sticky mucus to build up
in the lungs

Despite expanded use of current
products, lung function often
continues to decline

High treatment burden
major compliance issue

Source: Adapted from Cystic Fibrosis Foundation, Patient Registry
Annual Data Reports 2010

Mean = 51.2%

Pseudomonas Lung Infections Increase with Patient Age

Age (Years)

0.0

10.0

20.0

30.0

40.0

50.0

60.0

70.0

80.0

<2

2 to 5

6 to 10

11 to 17

18 to 24

25 to 34

35 to 44

45+

8

ARIKACE: Cystic Fibrosis

Need for New Inhaled Antibiotics

Current inhaled antibiotics produce modest efficacy in a limited patient

population providing an opportunity for ARIKACE to become first-line treatment

Current inhaled antibiotics are not indicated for a significant segment of the

CF population --

patients with FEV-1 % predicted of greater than 75%

Improvement in lung function with current inhaled antibiotics is not sustained

in the off-treatment period, and appears to decline over multiple cycles

Lung function continues to decline at an average rate of 1% to 3% per year with some patients experiencing much greater declines

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Cayston
®
vs. Tobi
®
CF Phase 3 Trial Results: Pulmonary Function
Lung Function
Adjusted

Mean
Relative
Change
in
FEV
1
%

Predicted

Source: 2010 North American CF Conference Poster 305 and Slide Presentation, 10/10.

* Cayston

®

(aztreonam

for

inhalation

solution)

is

a

registered

trademark

of

Gilead

Sciences.

** Tobi

®

(Tobramycin Inhalation Solution) is a registered trademark of Novartis.

*** AZLI = Cayston; TIS = Tobi

Lung function returned to baseline or lower during each off treatment

period and at the end of 24 weeks, both treatment groups showed a

decline in lung function from baseline

Week:

2

AZLI

TIS

+ 7.8

P

= 0.0001

95% CI (3.86, 11.73)

-6

-4

-2

0

2

4

6

8

10

12

0

4

8

12
16
20
24
AZLI/
TIS
28 Days
AZLI/
TIS
28 Days
AZLI/
TIS
28 Days

10
Off-Treatment
Period
P = 0.033
P = 0.003
(36/36)
(36/35)
(33/36)

(32/35)

(34/35)

(34/34)

(N=ARIKACE/Placebo)

ARIKACE: Cystic Fibrosis

Phase 2 Pooled Results (560mg QD): Pulmonary Function

(N)

Mean (SE)

ARIKACE demonstrated statistically significant and clinically meaningful improvement in pulmonary function throughout the 28-day treatment period that was sustained through the off-treatment period

-6%

-3%

0%

3%

6%

9%

12%

15%

18%

0

7

14

21

28

56

Visit Day

% Change in FEV

1

(ml) vs. Baseline

Arikace

560mg

Placebo

11

Visit Days

ARIKACE: Cystic Fibrosis

Open Label Extension (TR02-105): Durability of Response

Treatment

Period

* Significance at end of treatment over 6 cycles

** Significance 56 days off-treatment over 6 cycles

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An open label extension study demonstrated the sustained efficacy
of ARIKACE during and between multiple cycles of therapy

Patients Receiving 560 mg ARIKACE Once Daily for 28 Days and Off-Treatment for 56 Days

$p=0.0001^{**}$

$p<0.0001^{*}$

Cycle

1

Cycle

2

Cycle

3

Cycle

4

Cycle

5

Cycle

6

0

5

10

15

20

14

28

56

70

85

98

112

140

154

169

182

196

224

238

253

266

280

308

322

337

350

364

392

406

421

434

448

476

490
504

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ARIKACE: Cystic Fibrosis

Phase 3 Program Has Been Initiated in Europe and Canada

Insmed has reached agreement with EMA and Health Canada on pivotal study requirements for CF patients with Pseudomonas lung infections

* Patients who complete CLEAR-108 are eligible to participate in CLEAR-110, which is a long term open-label extension study in which patients receive ARIKACE every other month for up to 2 years

CLEAR-108: Phase 3 Primary Efficacy Study (vs. Tobo

®

, N

300)*

Primary End-Point: Relative Change in FEV-1 at week 24

Key Secondary End-Point: Time to First Pulmonary Exacerbation

Patient

Population:

Patients

ages

6

and

above

with

FEV-1

%

Predicted

25%

Approximately 260 patients required to demonstrate non-inferiority at agreed upon

Top-Line results projected in mid-2013

margin with 80% power

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ARIKACE: Non-TB Mycobacteria
Disease Description and High Unmet Need
NTM
are
intracellular
organisms
that

invade
and
multiply
chiefly
within
macrophages
in
the lung and are characteristically resistant to most antibiotics
NTM lung infections occurs commonly in patients with structural lung disease (e.g. COPD, bronchiectasis and CF), patients taking immunosuppressive medications, and in postmenopausal women without clear risk factors
NTM lung infections are often debilitating and progressive
Virtually all patients experience chronic or recurring cough
Other frequent symptoms including sputum production, fatigue, malaise, dyspnea, fever, hemoptysis, chest pain and weight loss
Non-TB mycobacteria (NTM) are intracellular pathogens that can cause severe, chronic pulmonary disease with limited effective treatment options
ATS -
American Thoracic Society;
IDSA -
Infectious Disease Society of America
Current
treatment
for
NTM
lung
disease
requires
lengthy
multi-drug
regimens
that
can
be
poorly
tolerated
and
have
limited
efficacy,
especially
in
patients
with
severe
disease
or
in
those
who

have
failed
prior
treatment
attempts
David
E.
Griffith,
M.D.,
Lead
author
of
the
ATS/IDSA's
diagnosis
and
treatment
guidelines
for
NTM,
and
Professor
of
Medicine
at
the
University
of
Texas
Health
Science
Center
at
Tyler;(Insmed
Press
Release,
6/27/12)

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ARIKACE: Non-TB Mycobacteria

Market Opportunity

The prevalence of this debilitating chronic disease continues to grow, and

the current NTM treatment paradigm lacks acceptable treatment options *

Sources: 1. Clarity Pharma Research, Patient Chart Study, 2012.

2.

Adjemian et al. Prevalence of Pulmonary Nontuberculous Mycobacterial Disease among Medicare Beneficiaries, USA, 1997-2007, American Journal of Respiratory and Critical Care Medicine. Apr 2012.

3. SDI Healthcare Database, July 2009.

Mycobacterium avium Complex; M. abscessus

Mycobacterium abscessus

U.S. Patients Diagnosed with NTM Lung Infections in 2011

50K

40K

21K

Diagnosis

growing

at~

8%

annually

2

MAC and M. abscessus* account for 75%-85% of NTM lung disease in U.S.

Mean age is ~ 57 years with 53%

treated

with

antibiotics

1

Treated patients use an average of 7.6

antibiotic

courses

per

year

3

Average length of inpatient hospital

stay

is

10.2

days

3

Patients over the age of 65 years were

40% more likely to die than those

without

NTM

from

1997

to

2007

2

* Mark Rolfe, M.D. FCCP, President of New Lung Associates P.A., Medical Director of the Lung Transplant and Adult Cystic Fibrosis Programs at Tampa General Hospital; Insmed press release, June 27, 2012

0

10,000

20,000

30,000

40,000

50,000
60,000
NTM Patients
Diagnosed
NTM Patients
Diagnosed with
MAC or M.
Abscessus
MAC & M.
abscessus
Patients Treated
with Anitbiotics
1

15

ARIKACE: Non-TB Mycobacteria

Rationale for ARIKACE

NTM lung infections are difficult to treat since NTM are taken up and multiply inside lung macrophages and most antibiotics have poor macrophage penetration

Amikacin IV is a recommended treatment for MAC and M. abscessus in the ATS/IDSA's NTM diagnosis and treatment

guidelines

1

but

use

is

limited

due

to

nephro-

and

oto-toxicity

The proprietary liposomal formulation enables ARIKACE to be

preferentially

taken

up

and

concentrated

in

the

lung

macrophages

while

potentially

decreasing systemic exposure and related toxicities

ARIKACE

was

shown

to

have

superior

in

vitro

activity

against

MAC

and

M.

abscessus

vs.

free

amikacin

2

ARIKACE

is

well

positioned

to

become

the

first

drug
approved
for
NTM
lung
infections

ARIKACE opportunity: achieve superior efficacy in NTM treatment by better penetrating lung macrophages where NTM bacteria reside while limiting systemic drug exposure

Sources: 1. Griffith et al. ATS/IDSA Statement: Diagnosis, Treatment, and Prevention of NTM Diseases, American Journal of Respiratory and Critical Care Medicine, 2007.

2.

Study conducted by L. E. Bermudez at Oregon State University. (Data on File)

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ARIKACE: Non-TB Mycobacteria
TARGET-NTM Clinical Study Initiated in Mid-2012
Trial Design and Patient Population (N
100):

Randomized, double-blind, placebo controlled Phase 2 study in patients with
recalcitrant/persistent NTM lung infections who are on a stable ATS/IDSA

guidelines-based multi-drug treatment regimen

Patients receive ARIKACE or placebo daily for 84 days; then all patients can receive ARIKACE 560 mg in an open-label manner for an additional 84 days

Study population: patients ages 18 to 75

Key Inclusion Criteria: History of chronic infection with either Mycobacterium avium complex

(MAC)

or

Mycobacterium

abscessus

or

mixed

infection

with

both

species

Primary endpoint: Change in mycobacterial culture results from baseline to end of treatment [Time

Frame:

84 days]

Insmmed appears to be the only company with an NTM clinical program;

top-line Phase 2 data projected in 4Q 2013

There have been very few clinical trials to support current NTM treatment recommendations, and no new drugs have been assessed in randomized trials for NTM lung disease in many years. (Insmmed Press Release, June 27, 2012)

according to Kenneth N. Olivier, M.D., M.P.H., Principal Investigator of the study and staff pulmonologist at the NIAID, part of NIH

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Projected
Cash at year
end 2012
(including cash,
investments & CD
)

Approximately \$60 to \$64 million currently forecast

We believe cash is sufficient to take Company through the availability of top-line data for both CLEAR-108 and TARGET-NTM top-line results

Current Overview: Capital Structure and Key Financials

Balance Sheet

Cash of ~\$75 million as of June 30, 2012 consisting of cash, investments & CD

Present Capital

Structure

(INSM)

26.5 million fully diluted shares:

24.9 million Common Shares

1.6 million options, restricted stock units, and warrants

Insmmed has a strong cash position

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Appendix
Addressing the Potential for Cross-Resistance of ARIKACE

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Summary: Addressing Potential for Cross-Resistance in
ARIKACE

While resistance to TOBI (tobramycin) has been [documented](#), we believe there is no cross-resistance in ARIKACE (amikacin) for the following reasons.

Well-characterized clinical isolates of *Pseudomonas aeruginosa* (Pa) from Dr. Burns collection have been tested against amikacin

and

ARIKACE.

ARIKACE

has
shown
activity
against
aminoglycoside-resistant
and
multi-drug
resistant
isolates.

Dr.

Burns

felt

ARIKACE performed a bit better than free amikacin. (Report on file.)

Overall, amikacin has lower potential for inducing resistance as compared to tobramycin (literature).

Additionally,

aminoglycoside-inactivating enzymes elaborated by Pa are different for these two aminoglycosides. Thus, there is no complete cross resistance. The issue of emerging tobramycin resistance secondary to TOBI (inhaled antibiotic) use is not completely quantified.

However,

it

is

primarily

due

to

poor

compliance

with

the

prescribed

regimen

of

TOBI.

Patients

do

not take

the drug twice a day consistently. This leads to drug levels much below the MICs of most phenotypes of Pa for prolonged periods and thus increased potential for emergence of resistance.

Additionally, there is non-specific binding of cationic tobramycin to

sputum and further low levels available to microbes. Typically, levels >10x of the MICs are needed for entire dosing interval.

Thus, compliance with dosing regimen is critical as is penetration of antibiotics into biofilms.

Features of ARIKACE that overcome some of the issues responsible

for resistance include: charge neutral liposomes shield

amikacin, providing penetration into biofilm, and high C_{max} and AUC, enabling once a day dosing and improved compliance.

unique features of ARIKACE will reduce potential for emergence of amikacin resistance vs. free aminoglycoside for inhalation.

Most importantly, the sustained clinical benefit of Arikace in the off month

and convenience of once a day will shape the use of

inhalation antibiotics in CF patients.

Use of ciprofloxacin is known to contribute to emergence of Pa isolates with antimicrobial resistance. Tobramycin is also used

IV
for
treatment
of
exacerbations
and
for
tune-ups.

This
may
also
be
contributing
to
emergence
of
resistance
as
low
levels
of
drug reach the lung after IV use.

Our phase 2 data have shown that 65% of isolates were resistant to aminoglycosides and ~90% were mucoid variant. However, we were able to demonstrate reduction in bacterial density and improvement in lung function and pros. Thus, we expect to have significant treatment effect in phase 3 studies even if isolates are resistant. We have also done in vitro work against mdr isolates and shown ARIKACE to be effective.

21
Percent Change in FEV
1
ITT
Visit Day
Arikace 560 *
15.4% (16.5)
18.4% (21.3)

13.2% (15.3)
13.2% (16.2)
11.5% (16.4)
13.2% (24.3)
Arikace 280 *
10.9% (10.6)
9.4% (12.6)
9.6% (12.5)
10.1% (12.8)
1.7% (9.0)
2.0% (8.6)
Placebo *
0.6% (11.7)
-3.2% (12.2)
1.8% (10.9)
2.2% (11.9)
-0.3% (12.0)
-4.4% (13.0)
* Mean (SD)
Arikace 280
Placebo
Arikace 560
p=0.016
p=0.005
p=0.07
p=0.04

22
Change in FEV
1
(% predicted) ITT
Visit Day
Arikace 560 *
12.9% (17.2)
15.8% (22.5)

10.5% (15.6)

11.0% (16.4)

8.6% (17.7)

13.8% (26.2)

Arikace 280 *

10.8% (10.8)

9.2% (13.1)

9.4% (12.9)

9.6% (13.7)

1.6% (9.6)

1.8% (8.8)

Placebo *

-0.9% (10.7)

-4.4% (11.3)

0.3% (9.9)

0.5% (10.5)

0.7% (9.6)

-3.8% (13.5)

Arikace 280

Placebo

Arikace 560

P=0.009

P=0.019

P=0.124

P=0.021

* Mean (SD)

23

ARIKACE TR02-05

PFT: Prior Use of Inhalation Antibiotic

Arikace

(N = 8)

Placebo

(N = 4)

Day 28

10 %

-5 %

Day 56

5 %

-1 %

Relative Change FEV

1

(ml)

24
Tobramycin
FEV
1
(L) Absolute

25
ARIKACE TR02-05
By Prior Tobramycin Use
Patients With Prior
Tobramycin Use
Patients Without Prior
Tobramycin Use
Arikace

N=5
Placebo
N=3
Arikace
N=16
Placebo
N=8
Day 28
0.326 (0.290)
5
-0.083 (0.123)
3
0.126 (0.203)
16
-0.016 (0.144)
8
Day 56
0.152 (0.186)
5
-0.040 (0.284)
3
0.001 (0.161)
15
-0.120 (0.168)
8
*
Absolute
Change
from
Baseline
-
FEV
1
(L)
Cohort I
280 mg

ARIKACE TR02-05
By Prior Tobramycin Use
26
* Mean (SD)
280mg Cohort
Patients without Tobramycin
280mg Cohort
Patients with Tobramycin

Arikace
Placebo
Arikace
Placebo
Visit Day
Visit Day
Arikace *
326 (290)
152 (186)
Placebo *
-83 (123)
-40 (284)
Arikace *
126 (203)
1 (161)
Placebo *
-16 (144)
-120 (168)
RUN12AUG2008
26

27
Tobramycin
FEV
1
(L) Relative

28
ARIKACE TR02-05
By Prior Tobramycin Use
Patients With Prior
Tobramycin Use
Patients Without Prior
Tobramycin Use
Arikace

N=5

Placebo

N=3

Arikace

N=16

Placebo

N=8

Day 28

0.136 (0.088)

5

-0.052 (0.075)

3

0.091 (0.138)

16

-0.002 (0.067)

8

Day 56

0.051 (0.093)

5

-0.010 (0.148)

3

0.009 (0.084)

15

-0.053 (0.083)

8

* Mean (SD)

*

Relative

Change

from

Baseline

-

FEV

1

(L)

RUN12AUG2008

Cohort I

280 mg

29
ARIKACE TR02-05
By Prior Tobramycin Use
* Mean (SD)
RUN12AUG2008
280mg Cohort
Patients without Tobramycin
280mg Cohort

Patients with Tobramycin

Arikace

Placebo

Arikace

Placebo

Visit Day

Visit Day

Arikace *

13.6% (8.8)

5.1% (9.3)

Placebo *

-5.2% (7.5)

-1.0% (14.8)

Arikace *

9.1% (13.8)

0.9% (8.4)

Placebo *

-0.2% (6.7)

-5.3% (8.3)

30

Arikace

-

Efficacy in Patients with Prior Tobramycin Use:

TR02-106

Mean

Change in Log

10

CFU

Subjects with 5-6 Cycles of TOBI in
prior 12 months

Change in FEV₁
(ml)

Subjects with 5-6 Cycles of TOBI in
prior 12 months

Placebo

Visit Day

Visit Day

Arikace 560

90 (220)

90 (30)

230 (60)

90 (90)

Placebo

-140 (210)

-110 (350)

-200 (20)

-290 (10)

Arikace 560

Arikace 560

-1.99

(0.70)

-1.26

(0.86)

-0.93

(1.19)

-1.43

(0.89)

-0.27

(0.44)

Placebo

0.15

0.03

-0.55

-0.29

0.08

Placebo

Arikace 560

Mean

-3

-2

-1

0

1

2

3

0

7

14
21
28
35
-300
-250
-200
-150
-100
-50
0
50
100
150
200
250
0
28
56
70
84

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Insmed has filed a registration statement (including a prospectus) with the Securities and Exchange Commission (the SEC) for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement and other documents Insmed has filed with the SEC for more complete information about Insmed and this offering. You may get these documents for free by visiting EDGAR on the SEC web site at www.sec.gov.

Alternatively,

Insmed

will

arrange

to

send

you

a

copy

of

the

prospectus

if

you request it by calling Insmed's corporate secretary at: (732) 997-4600.