
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 23, 2014

OPKO Health, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33528
(Commission
File Number)

75-2402409
(IRS Employer
Identification No.)

4400 Biscayne Blvd
Miami, Florida 33137
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (305) 575-4100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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ITEM 7.01. Regulation FD Disclosure.

On June 23, 2014, OPKO Health, Inc. (the “Company”) presented the information in the presentation posters attached hereto as Exhibits 99.1 and 99.2 at the 16th International Congress of Endocrinology and The Endocrine Society’s 96th Annual Meeting and Expo (ICE/ENDO 2014) in Chicago and discussed 6 month results of a Phase 2 dose-finding study evaluating the safety and efficacy of its novel long-acting human growth hormone product (Lagova™) to treat pediatric growth hormone deficiency disorder (GHD). The Company also announced positive interim six-month Lagova data from its Phase 2 dose-finding study in a press release issued on June 23, 2014. A copy of the press release regarding this announcement is attached as Exhibit 99.3 hereto and is incorporated herein by reference.

In addition, on June 24, 2014, the Company held a conference call and slide presentation webcast to review the data. A copy of the webcast slide presentation is furnished as Exhibit 99.4.

Statements made in the posters and presentations which are not historical are forward-looking statements that reflect management’s current views with respect to future events and performance and may include statements concerning plans, objectives, goals, strategies, future events or performance, and underlying assumptions. Such statements are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The fact that these materials are being furnished should not be deemed an admission as to the materiality of any information contained in the materials.

The information contained in Item 7.01 to this Current Report on Form 8-K and Exhibits 99.1, 99.2, 99.3 and 99.4 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company under the Act, unless expressly stated otherwise.

ITEM 9.01. Financial Statements and Exhibits.*(d) Exhibits*

<u>Exhibit Number</u>	<u>Description</u>
99.1	Company Presentation dated June 23, 2014.
99.2	Company Presentation dated June 23, 2014.
99.3	Press Release of the Company dated June 23, 2014.
99.4	Company Webcast Presentation dated June 24, 2014.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OPKO Health, Inc.

Date: June 24, 2014

By /s/ Adam Logal

Name: Adam Logal

Title: Senior Vice President,
Chief Financial Officer

EXHIBIT INDEX

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PHARMACOKINETICS AND PHARMACODYNAMICS PROFILE OF ONCE-WEEKLY, CTP-MODIFIED HUMAN GROWTH HORMONE (MOD-4023): PHASE 2 DOSE FINDING STUDY IN CHILDREN WITH GHD DEFICIENCY.

Gili Hart¹, Prof. Zvi Zadik², Dr. Klaudziya Radziuk³, Dr. Nataliya Zelinska⁴, Dr. Oleg Mallevsky⁵, Prof. Violeta Iotova⁶, Dr. Julia Skorodok⁷, Koren R.¹, Amitzi L.¹ and Fima E.¹

¹OPKO Biologics, Ramat Gan, Israel; ²Hadassah Medical Center, Jerusalem, Israel; ³Dr. Zvi Zadik, Prof. Zvi Zadik, Professor, Department of Pediatrics, Hadassah University Hospital, Jerusalem, Israel; ⁴Department of Pediatrics, Hadassah University Hospital, Jerusalem, Israel; ⁵Department of Pediatrics, Hadassah University Hospital, Jerusalem, Israel; ⁶Department of Pediatrics, Hadassah University Hospital, Jerusalem, Israel; ⁷Department of Pediatrics, Hadassah University Hospital, Jerusalem, Israel

Introduction

OPKO Biologics is a clinical stage public company developing biobetter long acting versions of existing therapeutic proteins utilizing a technology called CTP.

CTP – A Natural Peptide Created During Evolution to Enhance Longevity of the hCG Hormone

Any Short-Lasting Protein + CTP = Long-Lasting Protein

The technology involves fusion of the C terminus peptide of hCG to one or both ends of the target protein. The technology was clinically validated and proven as a safe and efficient way for increasing the half-life of several therapeutic proteins while maintaining their biological activity.

MOD-4023 Pharmacokinetics

Average MOD-4023 Weekly PK Profile

Comparative Pharmacokinetic Parameters

Units	MOD-4023 C ₁	MOD-4023 C ₂	MOD-4023 C ₃	hGH C ₁
T _{1/2}	hr	24.4	23.8	17.4
T _{1/2}	hr	51	51	8
C _{max}	ng/ml	822.3	840.8	254.2
AUC ₀₋₂₄	ng/ml*hr	13203.4	14070.3	2254.0
CTP ₀₋₂₄	ng/ml*hr	1.8E+05	1.9E+05	1.1E+05

Average hGH Daily PK Profile

Study Outline

Randomized, comparator-controlled Phase 2 study was conducted in up to 56 pre-pubertal, naïve GHD children receiving one of three MOD-4023 doses as once-weekly regimen (0.25, 0.48, 0.66mg/Kg per week) or daily hGH (34µg/Kg/day) as comparator arm in subcutaneous injections. In order to introduce naïve patients to the allocated MOD-4023 dose in a gradual manner, a stepwise dose increase approach was implemented. All patients randomized to receive one of the three MOD-4023 doses started treatment for 2 weeks with the low MOD-4023 dose and based on the patient's dose allocation, followed by a dose increase to the next dose level every two weeks until the final allocated dose was reached. Subsequently to the second dose administration of the targeted dose MOD-4023, GH, IGF-1 and IGF-BP3 concentrations were measured and PK-PD analysis was conducted utilizing a population based approach.

Sex	Age (yr)	Weight (kg)	Height (cm)	IGF-1 (ng/ml)	IGF-BP3 (ng/ml)	IGF-1 SDS	IGF-BP3 SDS
Male	7.0	22.0	125.0	100.0	100.0	0.0	0.0
Female	7.0	22.0	125.0	100.0	100.0	0.0	0.0
Male	7.0	22.0	125.0	100.0	100.0	0.0	0.0
Female	7.0	22.0	125.0	100.0	100.0	0.0	0.0
Male	7.0	22.0	125.0	100.0	100.0	0.0	0.0
Female	7.0	22.0	125.0	100.0	100.0	0.0	0.0
Male	7.0	22.0	125.0	100.0	100.0	0.0	0.0
Female	7.0	22.0	125.0	100.0	100.0	0.0	0.0
Male	7.0	22.0	125.0	100.0	100.0	0.0	0.0
Female	7.0	22.0	125.0	100.0	100.0	0.0	0.0

MOD-4023 Pharmacodynamics

IGF-1 Change From Baseline

IGF-1 SDS Weekly Profile Following MOD-4023 Administration

IGFBP-3 Weekly Profile Following MOD-4023 Administration

Conclusions

- ✓ MOD-4023 Once weekly treatment at three different doses demonstrated a pronounced PK and PD dose dependent response.
- ✓ MOD-4023 once-weekly treatment provided an excellent and extended PK and PD profile compared to daily hGH which was maintained for 7 days
- ✓ The changes observed in IGF-1 and IGF-BP3 demonstrate adequate stimulation of the GH-IGF-1 axes which were shown to be comparable to that observed with daily hGH treatment.

MOD-4023 Single Weekly Injection supports once weekly injection in pediatric GHD population and therefore can potentially promote proper growth.

Introduction

OPKO Biologics is a clinical stage company developing biobetter long acting versions of existing therapeutic proteins utilizing a technology called CTP.



The technology involves fusion of the C terminus peptide of hCG, which is a highly O-glycosylated peptide, to the target protein. CTP enabled the production of a long-acting hGH (MOD-4023), which supports a single weekly injection in growth hormone deficient patients. MOD-4023 is manufactured as a non-viscous liquid formulation.

Objectives

Characterization of MOD-4023 drug substance and drug product with respect to the protein quality attributes process reproducibility

Methods

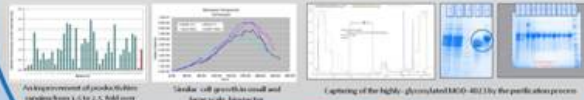
MOD-4023 characterization was carried out by applying various acceptable analytical methods including glycosylation profiling and peptide mapping. In Brief, for Peptide mapping assay, MOD-4023 was cleaved by trypsin generating specific peptides which are separated by RP-HPLC to obtain a specific fingerprint-pattern of MOD-4023. Glycoprofiling was performed by releasing MOD-4023 glycans followed glycan labeling with 2-aminobenzamide (ZAB), cleaned up and analyzed by NP-HPLC

Production of Long Acting hGH

Clone optimization - Performed by screening of commercial media, addition of different feeds and assessment of pH and temperature shift, using TubeSpin bioreactors.

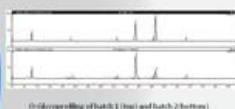
Production Bioreactor - In the production bioreactor cells are grown using a Fed-Batch mode in commercial chemically defined media including a commercially animal free feeding step, resulting in high productivity.

Purification Process - The down stream purification process is capturing and purifying the highly-glycosylated MOD-4023 exhibiting high capacity for removal of process related impurities including remarkable viral removal capacity.

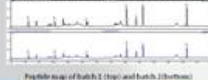


Characterization Studies

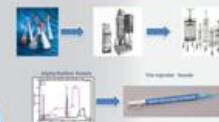
Glycoprofiling analysis of different batches shows that the major O-glycan structure in MOD-4023 is mono-sialylated core 1



Similar peptide map profiles of MOD-4023 batches are obtained supporting the consistency of the drug substance primary structure in each batch.



Conclusions



MOD-4023 manufacturing process is robust, producing a highly reproducible O-glycosylated product. Based on these findings and combined with its excellent safety profile and significant prolonged GH activity MOD-4023 has the potential to replace the daily injections of hGH now required for the treatment of GH deficiency with a weekly regimen.



OPKO Announces Positive Interim Six-Month Lagova™ (hGH-CTP) Phase 2 Data in Pediatric Growth Hormone Deficiency Disorder

Interim efficacy results show that a single weekly injection of Lagova (hGH-CTP) can replace seven consecutive daily injections of currently marketed human growth hormone (hGH)

Conference Call and Slide Presentation Webcast Scheduled Tuesday at 8:30am ET / 7:30am CT

Miami, FL – June 23, 2014 – OPKO Health, Inc. (NYSE:OPK), a multinational biopharmaceutical and diagnostics company, today announced 6 month results of a Phase 2 dose-finding study evaluating the safety and efficacy of its novel long-acting human growth hormone product (Lagova) to treat pediatric growth hormone deficiency disorder (GHD).

All three Lagova once-weekly doses demonstrate strong catch-up growth during the six months treatment. The annualized growth rates are above 12 cm in all three doses. The results are supported by excellent dose dependent pharmacokinetics (PK) and pharmacodynamics (PD) profiles. Lagova shows a promising safety profile with no serious adverse events reported. Glucose and lipid metabolism markers are within the normal ranges. No lipoatrophy was observed in any patients dosed, and no clinically significant local tolerability issues were identified.

“The interim results further affirm that a once-weekly administration of Lagova can replace daily injections of marketed hGH in pediatric GHD patients. The results enable dose selection for the company’s upcoming Phase 3 pediatric trial,” said Dr. Ron Rosenfeld, clinical advisor on the study and professor of Pediatrics (emeritus), Stanford University and professor of Pediatrics at Oregon Health and Science University (emeritus). “Because Lagova consists of native human growth hormone attached to a C-Terminal Peptide of endogenous hormone, one would anticipate low immunogenicity,” Rosenfeld noted.

“Based on these encouraging safety and efficacy results, OPKO plans to move aggressively into a single confirmatory pivotal Phase 3 study for pediatric GHD patients. We hope to make Lagova available to pediatric GHD patients as soon as possible,” said CEO, Phillip Frost, M.D. “Lagova is one of a family of important products being developed at OPKO Biologics designed to improve compliance and offer ease of administration to patients.”

Study Design

The randomized, comparator-controlled Phase 2 study was conducted in up to 56 pre-pubertal, naïve GHD children receiving one of three Lagova doses as once-weekly regimen (0.25, 0.48, 0.66mg/Kg/week; equivalent of 0.18, 0.35, 0.48 mg/Kg/week of hGH) or daily hGH (34µg/Kg/day) subcutaneously. In order to introduce naïve patients to the allocated Lagova dose in a gradual manner, a stepwise dose increase approach was implemented. Once patients reached the targeted doses, Lagova, GH, IGF-1 and IGF-BP3 concentrations were measured and PK-PD analysis was conducted utilizing a population based approach.

Study Results

An interim analysis of 6 months data demonstrated that all doses of Lagova used in the study provided strong catch-up growth response better than historical controls of daily growth hormone therapy.

The baseline characteristics of all patients were comparable among all groups. Interim analysis of the PK profile following administration of Lagova demonstrates a significantly extended half-life as reflected by the T1/2 and AUC respectively. A dose dependent PD (IGF-1) response was observed between Lagova cohorts, reaching steady state with no accumulation or excessive levels. All cohorts demonstrated promising “catch-up” growth, in line with reported age and GHD severity-matched data. The annualized height velocities are more than 12 cm, which correlates with the PK/PD profile in those patients.

Conference Call and Webcast

OPKO will hold a conference call and live webcast on Tuesday, June 24, 2014 at 8:30 a.m. EDT (7:30 a.m. CDT). The dial-in numbers are 1-877-407-0789 for domestic callers and 1-201-689-8562 for international callers. To join the live webcast of the presentation, please register for 'OPKO Health: ENDO Conference' on June 24, 2014, at 8:30 a.m. EDT (7:30 a.m. CDT) at:

<http://public.viavid.com/index.php?id=109688>

After the webcast, the call will remain available on the OPKO website, www.opko.com, for 30 days.

About Lagova (hGH-CTP)

In June 2013, OPKO initiated a pivotal Phase 3 clinical trial in adults for its proprietary long-acting version of hGH-CTP (Lagova). Lagova has been awarded orphan drug designation in the U.S. and Europe for both adults and children with growth hormone deficiency.

ABOUT OPKO HEALTH

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development and commercialization expertise and novel and proprietary technologies. For more information, visit <http://www.opko.com>.

SAFE HARBOR STATEMENT

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding expected results and benefits of Lagova, including its safety and efficacy, whether OPKO's clinical trials for adult and pediatric growth hormone deficiency will generate data to support marketing approval, whether a single injection of Lagova can replace seven consecutive daily injections of currently marketed hGH, whether Lagova will have low immunogenicity, the expected commencement date for the Phase 3 clinical trial for Lagova in pediatric patients, whether Lagova will be successfully developed or commercialized, expectations regarding the product and its market potential, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, including the risks that the Phase 3 clinical trials for the Lagova product may not be successful or achieve the expected results or effectiveness, and may not generate data that would support the approval or marketing of this product for the indications being studied, that others may develop products which are superior to Lagova, and that Lagova may not have advantages or prove to be superior over presently marketed products or products introduced in the future. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

OPKO Health, Inc.

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OPKO

June 2014

Cautionary Statement

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Ron G. Rosenfeld, MD

**Professor of Pediatrics (emeritus),
Stanford University**

**Professor of Pediatrics, Oregon Health &
Science University (emeritus)**

President, STAT5 Consulting, LLC



Lagova™

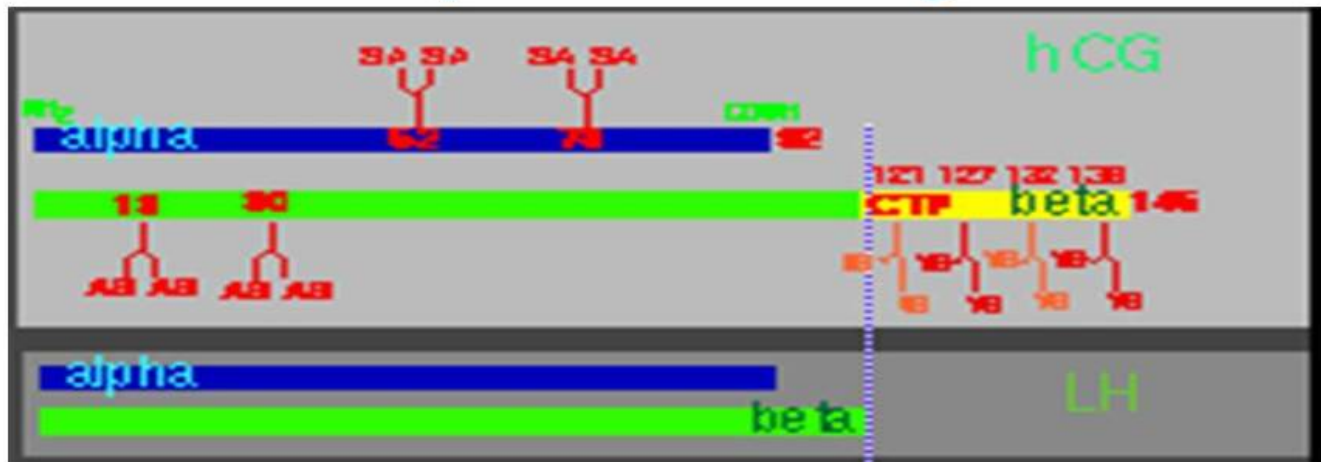
**The Long Acting Human Growth
Hormone**

ENDO 2014

OPKO Biologics Ltd.
Nes-Ziona, Israel

C-Terminal Peptide (CTP)

Created By Nature During Evolution



To Extend Circulation Time of
Functional Proteins

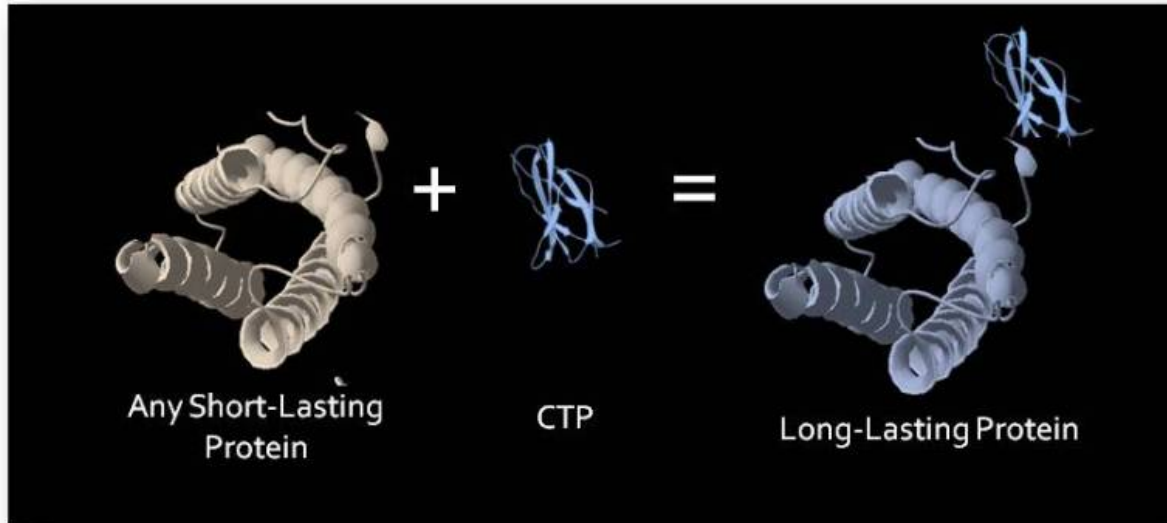
CTP: Clinically Validated Technology

CTP technology

has been used in an approved product
(Elonva[®], Once weekly FSH-CTP, Merck)

Lagova

The Long Acting Growth Hormone



Natural sequence
No need for linker

OPKO

PEGylation

- Increase size
- Slow enzymatic cleavage

DNA Mutations

- Add sugar chains
- Increase negative charge

Protein Fusion

- Increase size
- Slow enzymatic cleavage

Lagova

Competitive Advantages

Lagova

Potentially
non-immunogenic

Lagova

~75% native hGH

Lagova

Ease of administration

OPKO ⁹

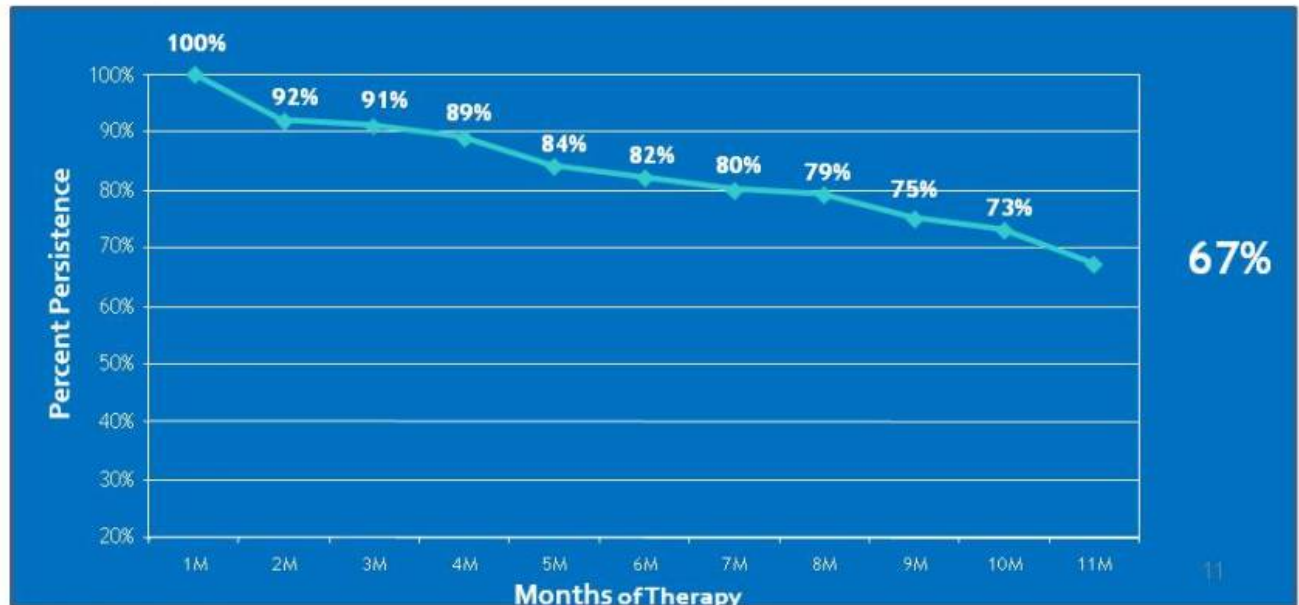
Lagova The Long Acting hGH

Global multi-center Phase 3 study in growth hormone deficient adults is ongoing

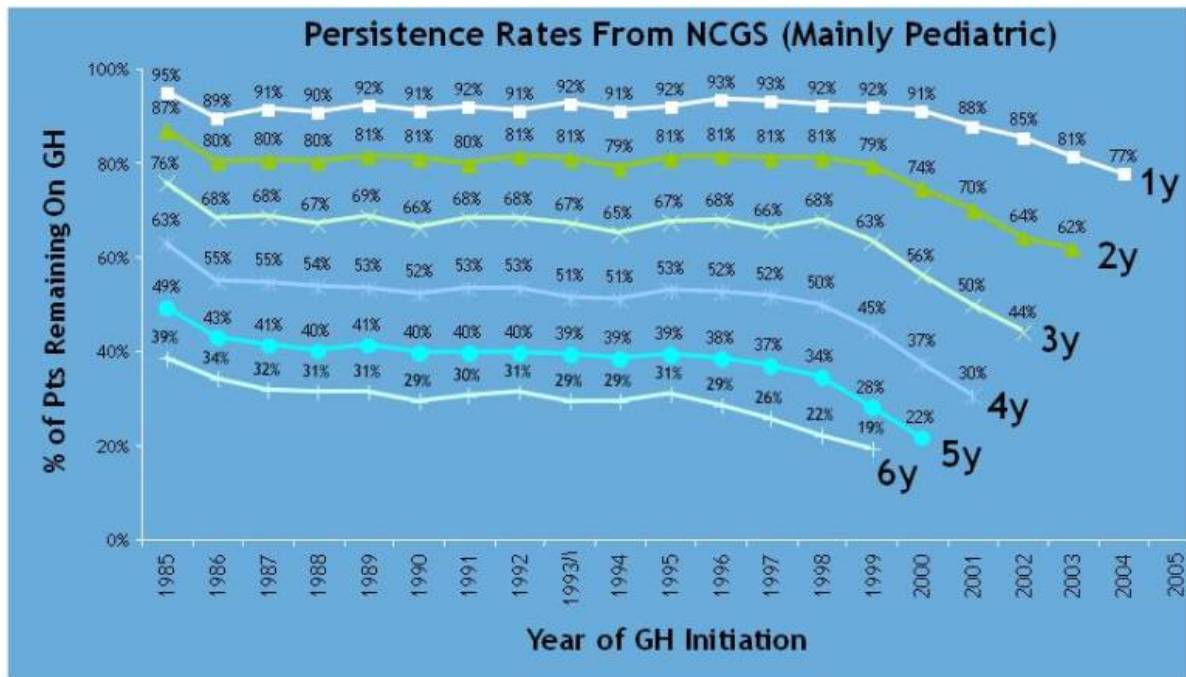
Compliance in Children Receiving Nutropin tend to reduce over time

Daily dosing is consistently found to have a baseline of non-compliance

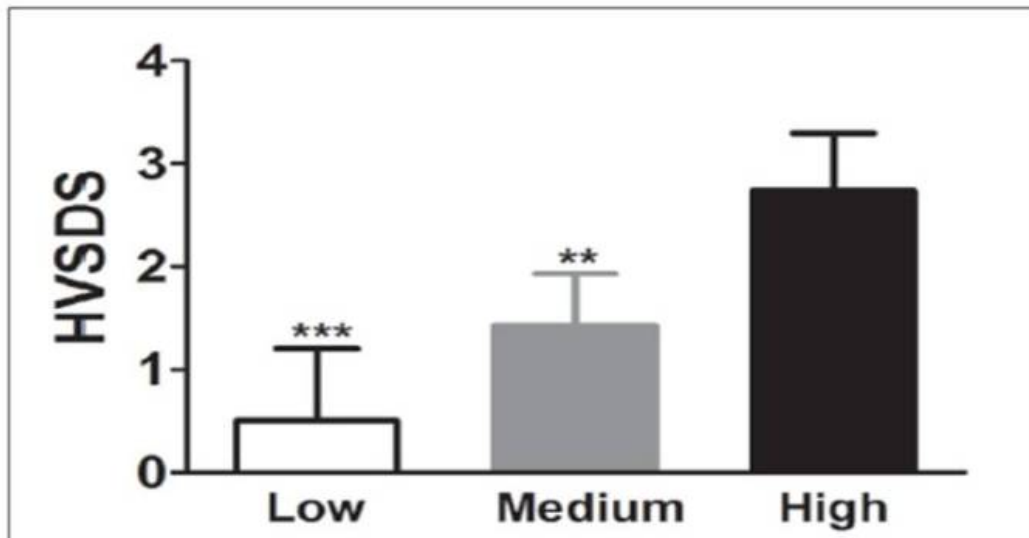
— Most pronounced in the pediatric population



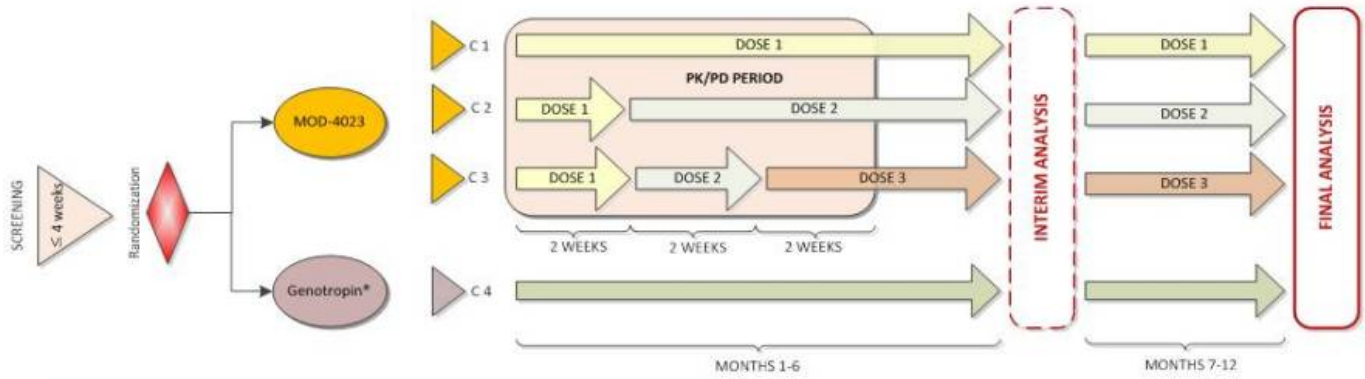
Persistence Rates Among Nutropin Patients Have Been Declining Steadily Over Time



Poor Compliance Leads to Slower Growth



Pediatric Phase 2 Study Design



C1 = 0.25 mg/kg/week (0.18 mg hGH/kg/week)

C2 = 0.48 mg/kg/week (0.35 mg hGH/kg/week)

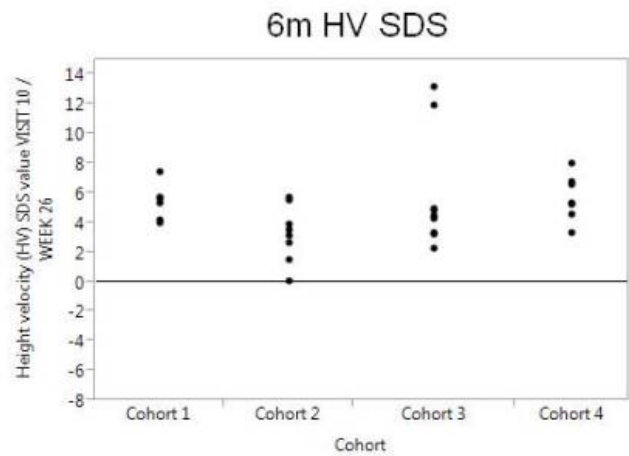
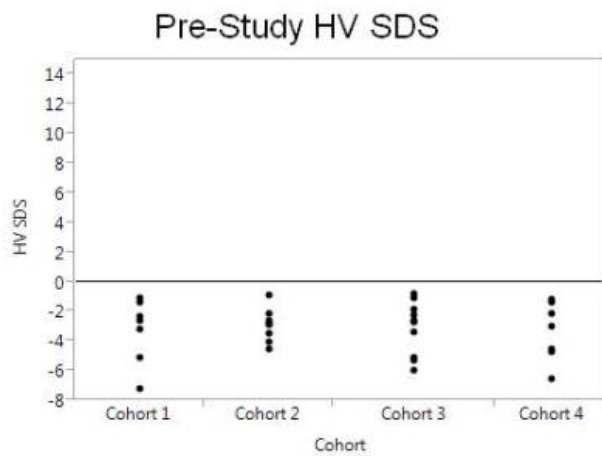
C3 = 0.66 mg/kg/week (0.48 mg hGH/kg/week)

C4 (hGH) = 0.24 mg/kg/week

Baseline Characteristics – Patients Completing 6 Months Treatment

Dose	Cohort 1 0.25 mg/kg/week Lagova		Cohort 2 0.48 mg/kg/week Lagova		Cohort 3 0.66 mg/kg/week Lagova		Cohort 4 0.034 mg/kg/day Genotropin	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
hGH content	0.18 mg/kg/week		0.35 mg/kg/week		0.66mg/kg/week		0.24 mg/kg/week	
N	9		9		10		7	
Age (y)	6.44	2.3	6.33	2.1	6.10	2.2	5.43	1.9
Peak GH (ng/ml)	2.84	2.9	3.58	1.7	4.41	3.2	2.92	2.4
HV SDS	-3.05	2.0	-2.82	1.1	-3.11	1.8	-3.36	2.0
HT SDS	-3.99	0.9	-3.82	0.8	-3.91	1.1	-4.79	1.7
HT SDS - TH SDS	-3.47	0.9	-3.23	0.7	-3.25	1.3	-4.20	1.8
Screening IGF-1 SDS	-2.48	0.8	-2.28	0.7	-1.81	0.7	-2.34	1.2
Gender (%)	F 1 (11.1)	M 8 (88.8)	F 4 (44.4)	M 5 (55.6)	F 3 (30)	M 7 (70)	F 3 (42.9)	M 4 (57.1)

Lagova Increases Height Velocity SDS Following 6m Treatment

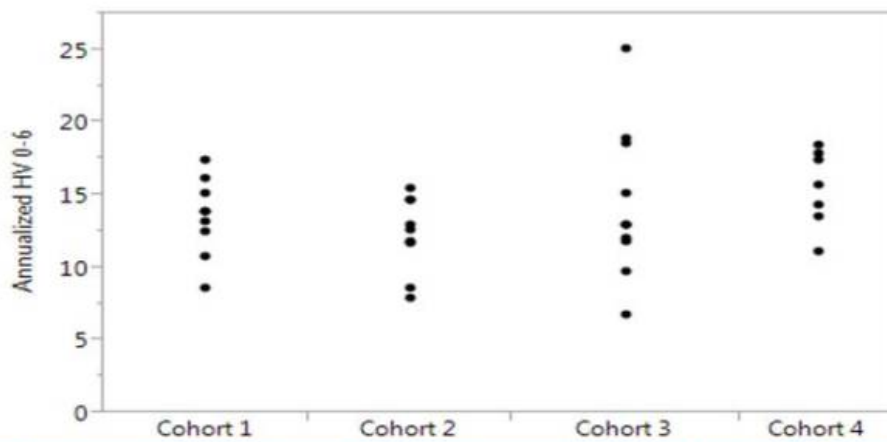


Cohort	Dose	N	Mean	Std Dev
Cohort 1	0.25 mg/kg/w Lagova™	8	-3.21	2.05
Cohort 2	0.48 mg/kg/w Lagova™	8	-2.94	1.14
Cohort 3	0.66 mg/kg/w Lagova™	10	-3.11	1.79
Cohort 4	0.034 mg/kg/d Genotropin	7	-3.36	1.98

Cohort	Dose	N	Mean	Std Dev
Cohort 1	0.25 mg/kg/w Lagova™	8	5.03	1.23
Cohort 2	0.48 mg/kg/w Lagova™	8	3.23	1.88
Cohort 3	0.66 mg/kg/w Lagova™	10	5.73	3.72
Cohort 4	0.034 mg/kg/d Genotropin	7	5.67	1.53

Lagova

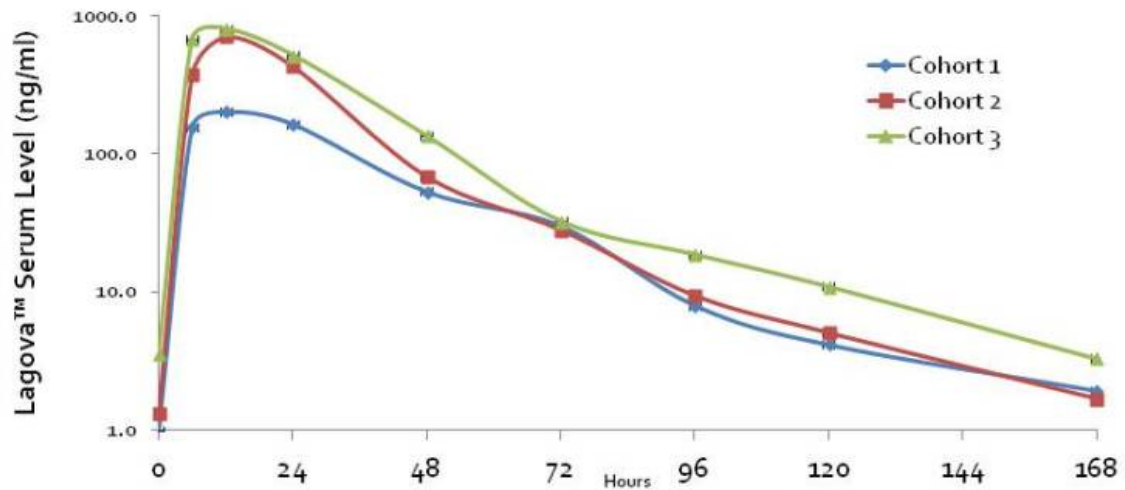
Increases Height Velocity in All Doses



Cohort	Dose	hGH Content	N	Mean (cm/year)	Std Dev
Cohort 1	0.25 mg/kg/w Lagova™	0.18 mg/kg/week	9	13.48	2.71
Cohort 2	0.48 mg/kg/w Lagova™	0.35 mg/kg/week	9	12.25	2.64
Cohort 3	0.66 mg/kg/w Lagova™	0.48 mg/kg/week	10	14.37	5.26
Cohort 4	0.034 mg/kg/d Genotropin	0.24 mg/kg/week	7	15.46	2.68

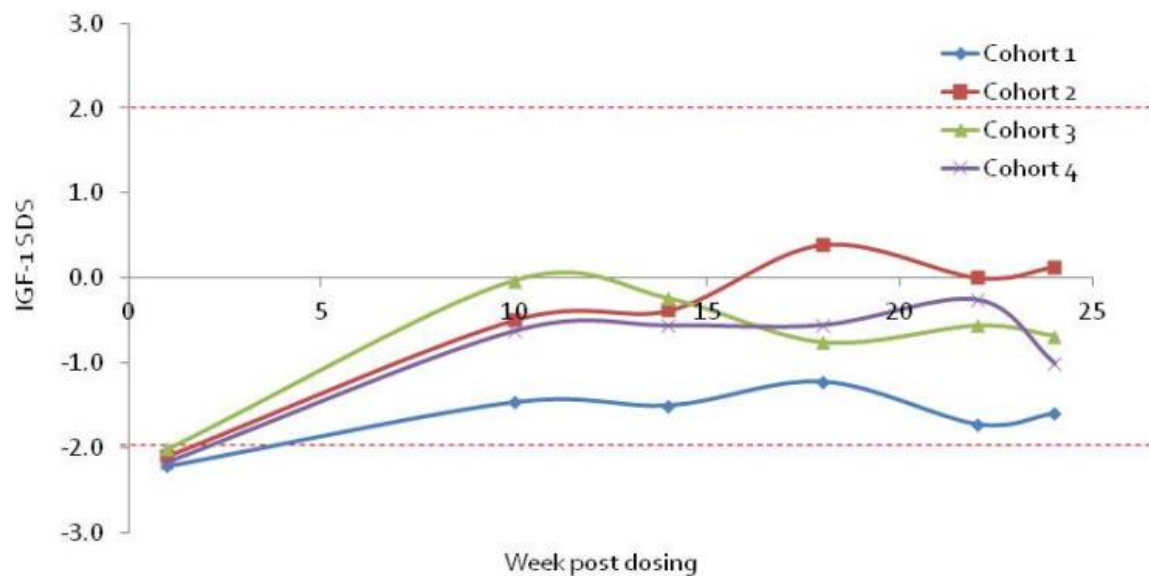
Lagova Pharmacokinetic profile

Average Lagova Weekly PK Profile (Cohort 1-3)



PK profile supports once-weekly regimen

Lagova Normalizes IGF-1 During the First 6 Months of Treatment



- ✓ IGF-1 SDS of Cohort 2 and 3 are comparable to daily hGH
- ✓ Gradual increase in IGF-1 SDS values reaching steady state within the normal range

Promising Safety Profile

- No serious adverse events
- No lipoatrophy
- No clinically significant local tolerability issues were identified.
- Comparable rate of AEs between Lagova groups and control group

Lagova The Long Acting hGH

Study supports safety and efficacy and allows selection of a dose for a Phase 3 study which is expected to start in 2015

Lagova The Long Acting hGH

- hGH content is ~75%
- CTP is a naturally occurring peptide
- Once a week injection
 - Non Viscous-30 - 31G needle
 - High concentrations-single weekly injection
- Address \$3.5B market at an annual growth of 6%

Thank You