

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 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): December 30, 2019**

**WAVE LIFE SCIENCES LTD.**

(Exact name of registrant as specified in its charter)

**Singapore**  
(State or other jurisdiction  
of incorporation)

**001-37627**  
(Commission  
File Number)

**Not applicable**  
(IRS Employer  
Identification No.)

**7 Straits View #12-00, Marina One East Tower**  
**Singapore**  
(Address of principal executive offices)

**018936**  
(Zip Code)

**Registrant's telephone number, including area code: +65 6236 3388**

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:

- 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
<b>\$0 Par Value Ordinary Shares</b>	<b>WVE</b>	<b>The Nasdaq Global Market</b>

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure.**

On December 30, 2019, Wave Life Sciences Ltd. (the “Company” or “Wave”) issued a press release announcing topline data and the addition of a higher dose cohort in the Company’s ongoing Phase 1b/2a PRECISION-HD2 clinical trial evaluating investigational WVE-120102 in patients with Huntington’s disease (HD).

In addition, the press release indicated that Wave management will host an investor conference call at 8:00 a.m. ET on December 30, 2019 to discuss the topline results. For purposes of the call, and in connection with the announcement described above, the Company provided an investor slide presentation (the “Investor Slide Presentation”) summarizing the topline results, which is available on the “For Investors & Media” section of the Company’s website at <http://ir.wavelifesciences.com/>. Copies of the press release and the Investor Slide Presentation are attached hereto as Exhibit 99.1 and Exhibit 99.2, respectively, and are incorporated by reference herein.

*The information in this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.*

**Item 8.01 Other Events.**

The information set forth in the press release, other than the second and fifth paragraphs thereof, is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit No.	Document
99.1	<a href="#">Press Release issued by Wave Life Sciences Ltd. dated December 30, 2019</a>
99.2	<a href="#">Investor Slide Presentation dated December 30, 2019</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

The portions of the press release incorporated by reference into Item 8.01 of this Current Report on Form 8-K are being filed pursuant to such item. The remaining portions of the press release are being furnished pursuant to Item 7.01 of this Current Report on Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that Section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as shall be expressly set forth by specific reference in such filing.

**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.

**WAVE LIFE SCIENCES LTD.**

By: /s/ Keith C. Regnante  
Keith C. Regnante  
Chief Financial Officer

Date: December 30, 2019



**Wave Life Sciences Announces Topline Data and Addition of Higher Dose Cohort in Ongoing Phase 1b/2a PRECISION-HD2 Trial in Huntington's Disease**

*WVE-120102 demonstrates statistically significant reduction in disease-causing mutant HTT protein in CSF vs. placebo*

*No difference in total HTT protein or neurofilament light chain in treated patients vs. placebo*

*Additional cohort expected to initiate in January 2020*

*Wave to host investor conference call and webcast at 8:00 a.m. ET today*

**CAMBRIDGE, Mass., December 30, 2019** – Wave Life Sciences Ltd. (Nasdaq: WVE), a clinical-stage genetic medicines company committed to delivering life-changing treatments for people battling devastating diseases, today announced topline data from the ongoing Phase 1b/2a PRECISION-HD2 trial evaluating investigational therapy WVE-120102, designed to be the first allele-selective approach to treat Huntington's disease (HD). In an analysis comparing all patients treated with multiple intrathecal doses of WVE-120102 to placebo, a statistically significant reduction of 12.4% ( $p < 0.05$ ) in mutant huntingtin (mHTT) protein was observed in cerebrospinal fluid (CSF). An analysis to assess a dose response across treatment groups (2, 4, 8 or 16 mg) suggested a statistically significant response in mHTT reduction at the highest doses tested ( $p = 0.03$ ). WVE-120102 was generally safe and well tolerated across all cohorts. These data support the addition of higher dose cohorts, and Wave expects to initiate a 32 mg cohort in January 2020.

“This topline analysis has given us the opportunity to evaluate early data from our ongoing dose finding study. The data demonstrate a reduction in mutant HTT and a safety and tolerability profile that supports exploration of higher doses of WVE-120102, with the goal of maximizing mutant HTT reduction and avoiding a negative impact on the healthy huntingtin protein,” said Michael Panzara, MD, MPH, Chief Medical Officer of Wave Life Sciences. “We plan to initiate the 32 mg cohort imminently and look forward to sharing data in the second half of 2020.”

WVE-120102 was developed as an allele-selective molecule, designed to preferentially lower mHTT protein by targeting single nucleotide polymorphism (SNP) rs362331 (SNP2) in order to keep the level of healthy or wild-type HTT (wtHTT) protein relatively intact. The wtHTT protein is important for neuronal function and may be neuroprotective in an adult brain. There is currently no assay available to directly measure wtHTT in the CSF; therefore, Wave is using an assay developed by CHDI Foundation, a not-for-profit biomedical research organization devoted to HD, to measure total HTT (tHTT) protein to indirectly assess effects on wtHTT. With this assay, a non-allele selective, pan-silencing approach would be expected to lead to a commensurate reduction in tHTT relative to mHTT.

While there was a statistically significant reduction in mHTT with WVE-120102 compared to placebo in the topline analysis, there was no difference in tHTT compared to placebo, suggesting WVE-120102 may have a potentially differential effect on huntingtin as measured by the mHTT and tHTT assays. Wave will continue to explore these potential effects with higher doses, where larger reductions of mHTT may be expected and where a more discernible impact on tHTT may be observed. Wave is continuing to work with CHDI Foundation and other research partners on methods to assess wtHTT protein preservation.

The topline analysis also assessed the presence of neurofilament light chain (NfL) in the CSF, and there was no difference in NfL between the WVE-120102 and placebo-treated groups. NfL is a protein component of the neuronal cytoskeleton. Its levels in the CSF are generally elevated when neurons are damaged in the setting of many neurological disorders, including HD.

WVE-120102 was generally safe and well tolerated among patients receiving doses up to 16 mg in both single and multidose portions of the study. A total of 72% of those who received WVE-120102 experienced an adverse event (AE) as compared with 83% on placebo, most of which were mild to moderate in intensity. The most common AEs (those occurring in at least 10% of patients on WVE-120102) were headache, procedural pain, falls and viral upper respiratory infection. There were no serious adverse events (SAEs) related to treatment with WVE-120102 and no study stopping rules were met, allowing dose escalation to continue. There were no notable changes in laboratory tests including liver or renal function tests, platelets or markers of immune activation.

PRECISION-HD2 is an ongoing, Phase 1b/2a multicenter, randomized, double-blind, placebo-controlled trial, which is evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple doses of WVE-120102 in adult patients with early manifest HD who carry SNP2. The trial included both single and multidose portions where patients were randomized to either WVE-120102 or placebo and received up to four intrathecal doses. The trial was designed for patients to receive a single dose and then undergo a washout period of at least eight weeks before entering the multidose portion which includes three monthly doses. Forty-four patients (31 WVE-120102 and 13 placebo) participated in the multidose portion and data from 39 patients (27 WVE-120102 and 12 placebo) were available for mHTT assessment as of data cut-off. In October 2019, Wave initiated an open-label extension (OLE) study open to patients outside of the U.S. who participated in the Phase 1b/2a PRECISION-HD2 trial and dosing of patients in the OLE is ongoing.

Wave is also conducting the PRECISION-HD1 Phase 1b/2a trial assessing WVE-120101 in early manifest HD patients who carry SNP rs362307 (SNP1). PRECISION-HD1 includes four cohorts (2, 4, 8 or 16 mg intrathecal doses). Given the PRECISION-HD2 results, PRECISION-HD1 will remain blinded and Wave plans to add a 32 mg cohort. Topline results from PRECISION-HD1, including those from the 32 mg cohort, are now expected in the second half of 2020.

### **Investor Conference Call and Webcast**

Wave management will host an investor conference call today at 8:00 a.m. ET to discuss these topline results. The conference call may be accessed by dialing (866) 220-8068 for participants based in the United States or +1 (470) 495-9153 for participants based outside the United States and entering conference ID 9594572. The live webcast may be accessed by visiting the investor relations section of the Wave Life Sciences corporate website at [www.ir.wavelifesciences.com](http://www.ir.wavelifesciences.com). Following the webcast, a replay will be available on the website.

### **About Huntington's Disease**

Huntington's disease (HD) is a debilitating and ultimately fatal autosomal dominant neurological disorder, characterized by cognitive decline, psychiatric illness and chorea. HD causes nerve cells in the brain to deteriorate over time, affecting thinking ability, emotions and movement. HD is caused by an expanded cytosine-adenine-guanine (CAG) triplet repeat in the huntingtin (HTT) gene that results in production of mutant HTT (mHTT) protein. Accumulation of mutant HTT causes progressive loss of neurons in the brain. Wild-type, or healthy, HTT (wtHTT) protein is critical for neuronal function and suppression may have detrimental long-term consequences. Approximately 30,000 people in the United States have symptomatic HD and more than 200,000 others are at risk for inheriting the disease. There are currently no approved disease-modifying therapies available.

### **About WVE-120101 and WVE-120102**

WVE-120101 and WVE-120102 are investigational stereopure antisense oligonucleotides designed to selectively target the mutant huntingtin (mHTT) mRNA transcript of SNP rs362307 (SNP1) and SNP rs362331 (SNP2), respectively. SNPs, or single nucleotide polymorphisms, are naturally occurring variations within a given genetic sequence and in certain instances can be used to distinguish between two related copies of a gene where only one is associated with the expression of a disease-causing protein.

In vitro studies in patient-derived cell lines have shown that WVE-120101 and WVE-120102 selectively reduce levels of mHTT mRNA transcript and protein, while leaving wild-type, or healthy, HTT mRNA transcript and protein relatively intact. The healthy transcript is required to produce wild-type HTT (wtHTT) protein, which is important for neuronal function, as evidenced by multiple preclinical studies indicating that long-term suppression of wtHTT protein may have detrimental consequences. Wave's allele-specific approach may also enable the company to address the pre-manifest, or asymptomatic, HD patient population in the future.

#### **About Wave Life Sciences**

Wave Life Sciences (Nasdaq: WVE) is a clinical-stage genetic medicines company committed to delivering life-changing treatments for people battling devastating diseases. Wave aspires to develop best-in-class medicines across multiple therapeutic modalities using PRISM™, the company's proprietary discovery and drug development platform that enables the precise design, optimization and production of stereopure oligonucleotides. Driven by a resolute sense of urgency, the Wave team is targeting a broad range of genetically defined diseases so that patients and families may realize a brighter future. To find out more, please visit [www.wavelifesciences.com](http://www.wavelifesciences.com) and follow Wave on Twitter @WaveLifeSci.

#### **Forward-Looking Statements**

This press release contains forward-looking statements concerning our goals, beliefs, expectations, strategies, objectives and plans, and other statements that are not necessarily based on historical facts, including statements regarding the following, among others: our commitment to advancing genetic medicines; our intent to add higher dose cohorts to PRECISION-HD2, including our plans to initiate a 32 mg cohort in January 2020 and to report that data in the second half of 2020; our intent to add higher dose cohorts to the Precision-HD1 trial, including a 32 mg cohort, and to report topline results from PRECISION-HD1, including those from the 32 mg cohort, in the second half of 2020; our ability to deliver on the promise of our current and future pipeline; the future performance and results of our programs in clinical trials and in preclinical development; and the benefit of nucleic acid therapeutics generally. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including the following: our ability to finance our drug discovery and development efforts and to raise additional capital when needed; the ability of our preclinical programs to produce data sufficient to support our clinical trial applications and the timing thereof; our ability to continue to build and maintain the company infrastructure and personnel needed to achieve our goals; the clinical results of our programs, which may not support further development of product candidates; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; our effectiveness in managing future clinical trials and regulatory processes; the effectiveness of PRISM; the continued development and acceptance of oligonucleotides as a class of medicines; our ability to demonstrate the therapeutic benefits of our candidates in clinical trials, including our ability to develop candidates across multiple therapeutic modalities; our dependence on third parties, including contract research organizations, contract manufacturing organizations, collaborators and partners; our ability to manufacture or contract with third parties to manufacture drug material to support our programs and growth; our ability to obtain, maintain and protect intellectual property; our ability to enforce our patents against infringers and defend our patent portfolio against challenges from third parties; and competition from others developing therapies for similar uses, as well as the information under the caption "Risk Factors" contained in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) and in other filings we make with the SEC from time to time. We undertake no obligation to update the information contained in this press release to reflect subsequently occurring events or circumstances.

#### **Investor Contact:**

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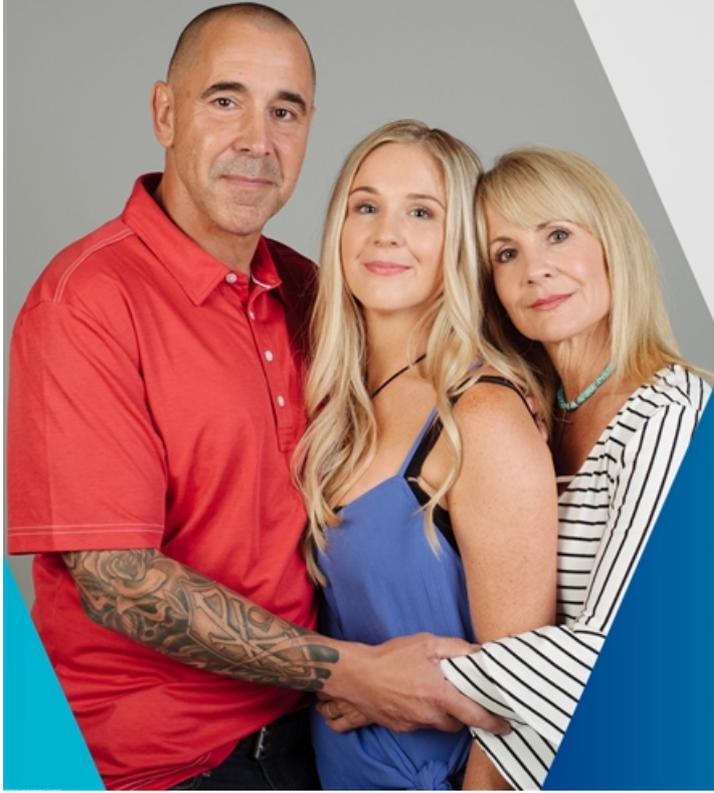
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# PRECISION-HD2 Topline Results

December 30, 2019

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# Forward-looking statements

This document contains forward-looking statements. All statements other than statements of historical facts contained in this document, including statements regarding possible or assumed future results of operations, preclinical and clinical studies, business strategies, research and development plans, collaborations and partnerships, regulatory activities and timing thereof, competitive position, potential growth opportunities, use of proceeds and the effects of competition are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause the actual results, performance or achievements of Wave Life Sciences Ltd. (the "Company") to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this presentation are only predictions. The Company has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that it believes may affect the Company's business, financial condition and results of operations. These forward-looking statements speak only as of the date of this presentation and are subject to a number of risks, uncertainties and assumptions, including those listed under Risk Factors in the Company's Form 10-K and other filings with the SEC, some of which cannot be predicted or quantified and some of which are beyond the Company's control. The events and circumstances reflected in the Company's forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, the Company operates in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that the Company may face. Except as required by applicable law, the Company does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

# Agenda

<b>Paul Bolno, MD, MBA</b> President & CEO   Wave Life Sciences	<b>Opening Remarks</b>
<b>Michael Panzara, MD, MPH</b> Chief Medical Officer   Wave Life Sciences	<b>PRECISION-HD2 topline results and clinical trial expansion</b>
<b>Paul Bolno, MD, MBA</b> President & CEO   Wave Life Sciences	<b>SNP3 and closing remarks</b>
<b>Q&amp;A</b>	

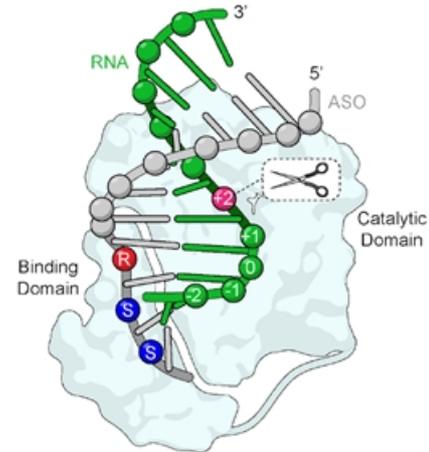
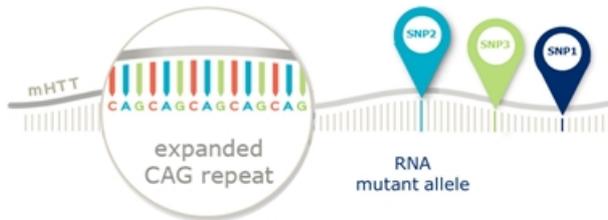




# Wave approach: novel, allele-selective silencing

Aims to lower mHTT transcript while leaving healthy wild-type HTT relatively intact

- Utilize association between single nucleotide polymorphisms (SNPs) and genetic mutations to specifically target errors in genetic disorders, including Huntington's disease (HD)
- Potential to provide treatment for up to 80% of HD population



**Allele-selectivity possible by targeting SNPs associated with expanded long CAG repeat in HTT gene**

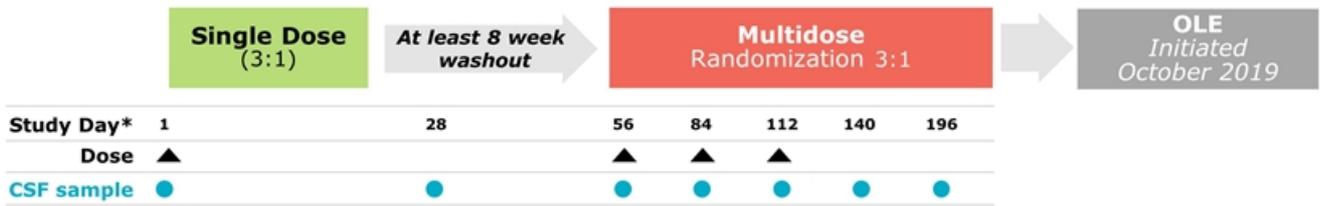
The image features a blue and white abstract geometric background with overlapping triangles and lines. In the top left corner, the company logo is displayed. The logo consists of the word "WAVE" in a large, white, sans-serif font, with a small "TM" trademark symbol to its upper right. Below "WAVE", the words "LIFE SCIENCES" are written in a smaller, white, sans-serif font.

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Michael Panzara, MD, MPH  
Chief Medical Officer

# PRECISION-HD2 clinical trial design

## Phase 1b/2a trial



### Multidose Cohorts

N = 12 per cohort



### As of data cut-off:

- 44 patients participated in multidose portion
- 39 had data available for mHTT assessment
  - 10 patients had not reached Day 140

# WVE-120102 generally safe and well tolerated

- A total of 72% of those who received WVE-120102 experienced an adverse event (AE) as compared with 83% on placebo, mostly mild to moderate in intensity
- Most common AEs (those occurring in at least 10% of patients on WVE-120102) were headache, procedural pain, falls, and viral upper respiratory infection
- No serious adverse events related to treatment and no stopping rules met
- No notable changes in laboratory tests including liver or renal function tests, platelets, or markers of immune activation
- Supports the addition of higher dose cohorts



# Significant reduction in CSF mHTT

## WVE-120102 compared to placebo

	Pooled Placebo (N=12)	Pooled WVE-120102 (N=27)
Median (% Change from Baseline)	9.5	-6.0
95% CI (%)	1.77, 20.38	-9.57, 4.85
<b>Difference (%)*</b>		<b>-12.4</b>
<b>95% CI (%)</b>		<b>-24.58, -0.40</b>
<b>p-value<sup>†</sup></b>		<b>&lt;0.05</b>

\*Hodges-Lehmann non-parametric shift estimates of the difference between treatment and placebo  
<sup>†</sup>Wilcoxon-Mann-Whitney non-parametric significance test

- Pooled analysis performed for all WVE-120102 treated patients compared to placebo demonstrated 12.4% statistically significant reduction in mHTT
- Statistical analysis across treatment groups using all available data from each cohort suggests dose response at the highest doses tested (p=0.03)



# Total HTT

## WVE-120102 compared to placebo

- Healthy or wild-type HTT transcript is required to produce healthy HTT protein which is important for neuronal function
- There is currently no assay available to directly measure wtHTT in the CSF
- Total HTT assay, developed by CHDI Foundation, measures total HTT protein to indirectly assess effects on wtHTT
  - With this assay, a non-allele selective, pan-silencing approach would be expected to lead to a commensurate reduction in tHTT relative to mHTT
- While there was a statistically significant reduction in mHTT compared to placebo in the topline analysis, there was no difference in tHTT compared to placebo, suggesting WVE-120102 may have a potentially differential effect on HTT
  - Wave plans to explore this with higher doses, where larger reductions of mHTT are expected and where a more discernible impact on tHTT may be observed



wtHTT: wild-type HTT

tHTT: total HTT

CSF: cerebrospinal fluid

# Neurofilament light chain

- Neurofilament light chain (NfL) is an indicator of axonal damage and is elevated in many neurological disorders, including Huntington's disease
- No change in CSF neurofilament light chain (NfL) between WVE-120102 and placebo-treated groups

# Advancing PRECISION-HD programs

## **PRECISION-HD2 (WVE-120102)**

- WVE-120102 demonstrated statistically significant reduction in mutant HTT compared to placebo
- Topline data support advancing to higher doses
- No difference in total HTT or neurofilament light chain in treated patients compared to placebo
- Data from 32 mg cohort expected in 2H 2020

## **PRECISION-HD1 (WVE-120101)**

- PRECISION-HD1 trial will remain blinded
- Additional 32 mg dosing cohort planned
- Topline results (including 32 mg cohort) now expected in 2H 2020

The image features a stylized background composed of overlapping geometric shapes in various shades of blue and teal. In the upper left corner, the company logo is displayed. The logo consists of the word "WAVE" in a large, white, sans-serif font, with a small "TM" trademark symbol to its upper right. Below "WAVE", the words "LIFE SCIENCES" are written in a smaller, white, sans-serif font.

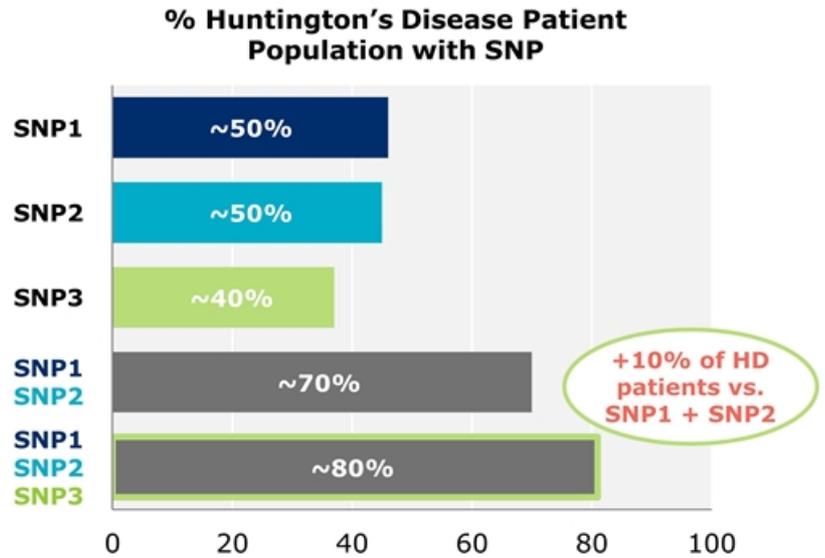
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Paul Bolno  
President and CEO

# SNP3: Broadening reach in Huntington's disease

## SNP3

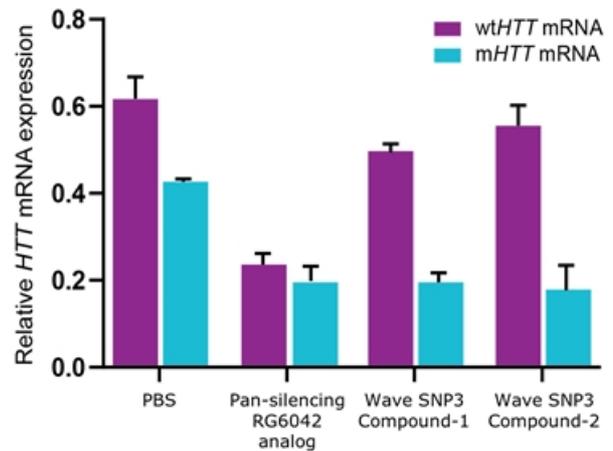
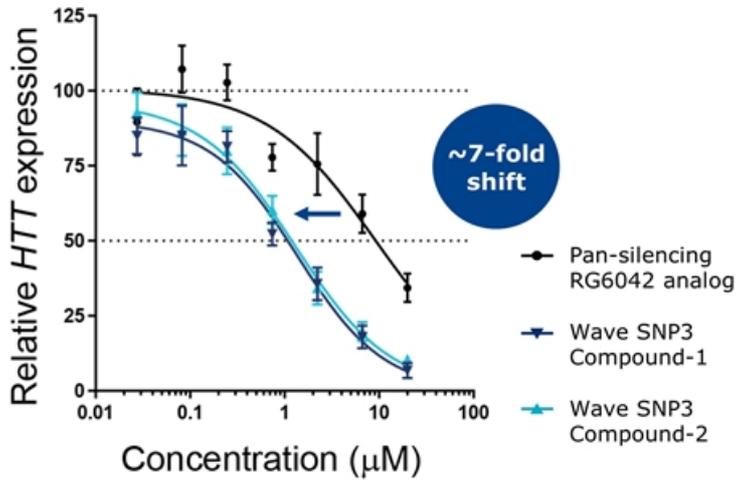
- Due to overlap, ~80% of the total HD patient population carry SNP1 and/or SNP2 and/or SNP3
- *In vivo* models for SNP3 available for preclinical development



# SNP3: Potent mutant HTT knockdown activity and demonstration of allele-selective silencing

Wave allele-selective compounds are more potent than pan-silencing RG6042 analog in preclinical study involving homozygous patient-derived neurons

Stereopure compounds selectively deplete mutant *HTT* mRNA in preclinical study involving heterozygous patient-derived neurons

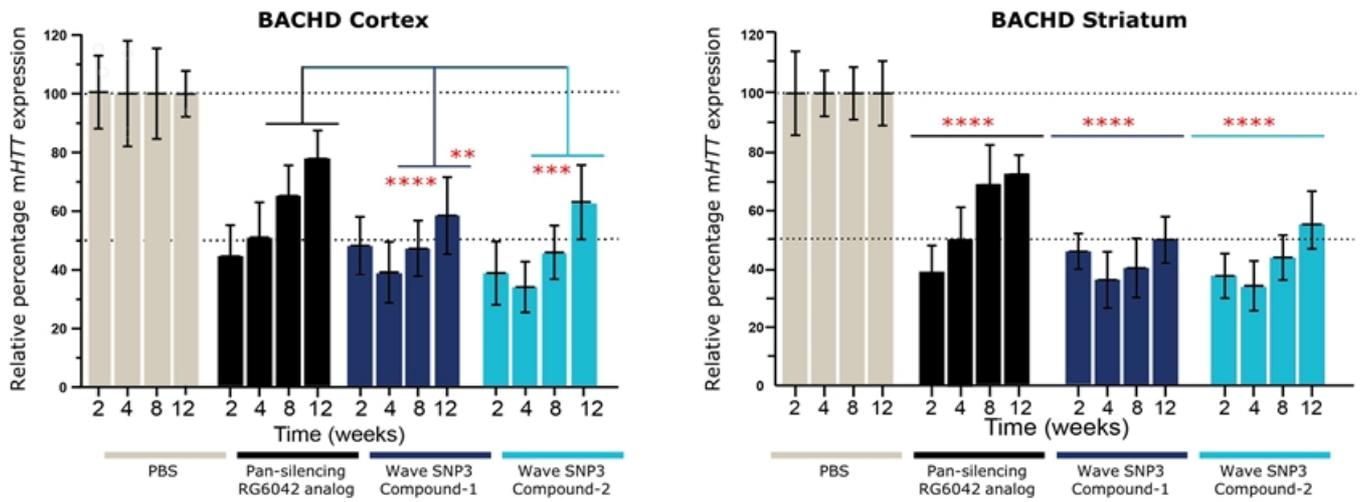


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[Left] HTT mRNA remaining in iCell neurons (homozygous for SNP) incubated with the indicated ASO under free-uptake conditions. Data show mean ± sem (n=4).  
[Right] Neurons were derived from GM21756 patient-derived fibroblasts (heterozygous for SNP) and treated with 20 µM of the indicated ASO under gymnotic conditions for 7 days. RNA was quantified and normalized to *TUBB3*. Data are mean ± sem (n=3). Percentage of remaining wtHTT and mHTT mRNA is indicated.

# SNP3: Durable *in vivo* mutant *HTT* knockdown with stereopure compounds

## Knockdown persists for 12 weeks



BACHD model only has mutant *HTT* (no wild-type *HTT*)



Oligonucleotide or PBS (3 x 100 mg ICV) was delivered to BACHD mice. Relative percentage of *HTT/TUBB3* mRNA in cortex with respect to levels in PBS-treated mice is shown at 2-12 weeks post-injection. Statistics: All oligo treatment groups are statistically significantly different from PBS; One-way ANOVA \*\*\*\*,  $P \leq 0.0001$ . Wave SNP3 Compound-1 and Compound-2 are also significantly different from RG6042 analog at 8 and 12 weeks \*\*\*,  $P < 0.005$ ; \*\* $P = 0.001$ .

# Anticipated upcoming Wave milestones

## CNS

- **2H 2020:** PRECISION-HD2 data from 32 mg cohort in Huntington's disease
- **2H 2020:** PRECISION-HD1 topline data, including 32 mg cohort, in Huntington's disease
- **2H 2020:** Initiate clinical development of SNP3 program in Huntington's disease
- **2H 2020:** Initiate clinical development of C9orf72 program in ALS and FTD

## Ophthalmology

- **2020:** Advance USH2A exon-skipping program

## RNA-editing

- **2020:** *In vivo* ADAR editing data

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Q&A



# PRECISION-HD2 Topline Results

December 30, 2019

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