V1aduct

A Phase 3 24-week study of balovaptan compared with placebo in adults with autism with a 2-year open label extension (NCT03504917)

WHAT WAS THE V1ADUCT STUDY?

- **V1aduct** looked at the **safety, tolerability, and effectiveness** of balovaptan compared with a placebo in autistic adults
- The study measured changes in **socialisation and communication** skills 24 weeks after starting the medicine

322 adults with moderate-to-severe symptoms of autism*,†

46 clinics across six countries

WHAT WERE THE RESULTS?

- The **study was stopped early** (after 50% of participants completed Week 24) as initial results showed that balovaptan was unlikely to give a meaningful improvement in socialisation and communication skills‡
- At Week 24, **people taking balovaptan did not improve more** in their socialisation and communication skills than people who took a placebo
  - This was measured by the Vineland™-II two domain composite score, which assesses aspects of socialisation and communication, such as how well a person interacts with others and how well they understand language
- On average, the scores of people in the balovaptan group improved by 4.56 points, and the scores of people in the placebo group improved by 6.83 points at Week 24

WHAT WERE THE SIDE EFFECTS?

- Balovaptan was **well-tolerated** with **no safety concerns** – there were **no significant differences** in the number of side effects experienced by people taking balovaptan compared with people taking a placebo
- Around 17% of people taking balovaptan and 16% of people taking a placebo had a side effect that was not considered serious
- No one in this study had **serious side effects** in either the balovaptan or the placebo groups

Five most common side effects§	People taking balovaptan (163 people total)	People taking placebo (158 people total)
Feeling tired	2%	2%
Feeling sleepy/drowsy	2%	1%
Feeling dizzy	Less than 1%	2%
Feeling sick	1%	1%
Increased appetite	2%	Less than 1%

Your meaningful contribution to our research efforts

We would like to thank the individuals and families who took part in the V1aduct study and gratefully acknowledge the efforts of everyone involved

Although there was no medicine-related improvement in social communication, this study was very valuable for researchers to learn more about autism and of ways to improve health outcomes and quality of life for people with autism

What will happen to my data?

- The anonymised aggregated data from this study have been published in the scientific journal 'The Lancet Psychiatry', *https://doi.org/10.1016/S2215-0366(21)00429-6*

Where can I find more information?

You can find more information about this study on the websites listed below:

- https://clinicaltrials.gov/ct2/show/results/NCT03504917
- https://forpatients.roche.com/en/trials/neurodevelopmental-disorder/autism-spectrum-disorder/a-study-of-balovaptan-in-adults-with-autism-spectrum-disorder-wi.html
- https://medinfo.roche.com/

Any further questions?

- Please contact a representative at your local Roche office

*Measured by Social Responsiveness Scale™, second edition (SRS-2) ≥66, Diagnostic and Statistical Manual of Mental Disorders, 5th edition, and Autism Diagnostic Observation Scale criteria; †322 participants took part but only 321 were given balovaptan or placebo due to the study being stopped early; ‡Some people in the balovaptan and placebo groups had chosen to keep taking or start taking balovaptan after Week 24 – this is called an open-label extension. When the study ended early, the people taking part in the open-label extension had to stop taking balovaptan too. §Side effects described are the most common side effects across both balovaptan and placebo groups and are considered related to treatment.

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