Axovant is focused on the development of novel therapeutics for the treatment of dementia, including Alzheimer's disease and Lewy body dementia. Our vision is to become the leading company focused on the treatment of dementia by addressing all forms and aspects of this condition.

As part of our work, we conduct clinical trials to evaluate the safety and efficacy of investigational drug candidates. If those clinical trials succeed, we would be allowed to apply for the required regulatory approvals in order to make those drugs widely accessible to patients in areas of great unmet need.

Axovant encourages awareness of and participation in our clinical trials. Please visit http://axovant.com/clinical-trials/ for more information about our clinical programs. Clinical trials are controlled research studies in humans designed to determine if an investigational drug candidate is safe and effective, and we believe that participating in clinical trials is the best way for patients to access investigational drug candidates before regulatory approval.

In certain cases, when it is not possible for a patient to participate in a clinical trial and all other available medical options have been exhausted, a patient's doctor may attempt to seek special access to an investigational drug candidate for that patient outside of a clinical trial—this is known, among other terms, as expanded access. Making decisions about requests for expanded access to an investigational drug candidate is a complicated, multi-faceted, and fact-heavy decision. This is because investigational drug candidates—which, by definition, have not yet obtained regulatory approval—may present numerous risks for the patient and the clinical development program. For patients, expanded access may involve potential safety risks or offer false hope. Likewise, for the clinical development program, expanded access may be cost-prohibitive, or delay or jeopardize the approval of a new treatment. For these and other reasons, Axovant at this point in time does not have an expanded access program.

Decisions regarding expanded access depend on nature of the request, the patient's health, the available medical and scientific information about the investigational drug candidate, the likelihood and timing of regulatory approvals, and—most importantly—any potential risk to a patient's health. Inclusion in an expanded access program, or a single request for expanded access of an investigational drug candidate, would be possible only if all of the following criteria are met:

- The patient has a serious or life-threatening illness
- There are no other therapies available
- The patient is ineligible for or cannot participate in a clinical trial
- The investigational drug candidate is currently being studied in clinical trials
- There is sufficient preliminary evidence to support an assessment that the potential benefits of making the investigational drug candidate to the patient outweigh the potential risks. This includes having adequate preliminary efficacy and safety data in order to make that determination—this would not occur before, at the very earliest, the end of Phase 2b studies
- There is adequate clinical data to determine an appropriate dose
- The patient has a disease or condition that is similar in type and stage to the indication(s) for which the investigational drug candidate is currently being studied by Axovant and for which there is sufficient evidence to expect that the patient will experience a clinically meaningful benefit

- Providing the investigational drug candidate through expanded access will not interfere with the initiation, conduct, or completion of clinical trials or regulatory approval of the investigational drug candidate
- There is sufficient amount of drug supply available to support both ongoing clinical trials and any approved expanded access
- The expanded access will occur in a country where Axovant expects to file for regulatory approval and in accordance with the requirements of the national regulatory authority
- The request must be made by the patient's treating doctor, unsolicited by Axovant or any other individual or organization.

Based on the above criteria, Axovant at this point has not established such a program and is not accepting requests for expanded access.

If a treating doctor finds that expanded access may be the only option for a patient, the doctor should formally contact Axovant to make a written request. Questions about or requests for expanded access to Axovant investigational drug candidates can be submitted to: expandedaccess@axovant.com. In the correspondence, the requesting doctor must agree to obtain appropriate regulatory and ethics committee approvals, if applicable, and to comply with all other safety, monitoring, and patient consent requirements defined by Axovant. Requests for expanded access may only be made by licensed doctors, in the country where the patient resides. Axovant will acknowledge receipt of requests within 3 business days. However, at this point, Axovant is not accepting requests for expanded access.

For further information on available expanded access programs, visit www.clinicaltrials.gov and search "expanded access programs".

Axovant's current clinical trials include:

1. Study Evaluating Intepirdine (RVT-101) in Subjects With Mild to Moderate Alzheimer's Disease on Donepezil: MINDSET Study (https://clinicaltrials.gov/show/NCT02585934)
2. Study Evaluating Intepirdine (RVT-101) in Subjects With Dementia With Lewy Bodies: The HEADWAY-DLB Study (https://clinicaltrials.gov/show/NCT02669433)
3. Study Evaluating Intepirdine (RVT-101) on Gait and Balance in Subjects With Dementia (https://clinicaltrials.gov/show/NCT02910102)
4. Study Evaluating Nelotanserin for Treatment of Visual Hallucinations in Subjects With Lewy Body Dementia (https://clinicaltrials.gov/show/NCT02640729)
5. Study Evaluating Nelotanserin for Treatment of REM Sleep Behavior Disorder in Subjects With Dementia With Lewy Bodies (https://clinicaltrials.gov/show/NCT02708186)