
“One moon dispels the darkness,
not thousands of stars”

Chanakya



WE ARE VESTRA

FAMOUS FOR CLINICAL EXCELLENCE

- **Specialized in Alzheimer's Disease**
 - **Outstanding Clinical Research**
- **Committed to Patient Recruitment**
 - **Efficient & Accurate Service**

Testimonials – Experience with us

These testimonials from our partners highlight how collaboration with our team enables delivery of exemplary clinical research.



October 7th, 2021

This memo is to confirm the participation of Vestra Clinics in the PUCINI study that assess the efficacy and safety of BAY 1817080 in patients with diabetic neuropathic pain. The Principle Investigator was Dr. Ladislav Pazdera.

Dr. Pazdera and his team was the highest enrolling site in the study globally. They successfully screened 19 patients and randomized 15 patients.

Dr. Pazdera's site met all timelines and was significant contributor to the study.

Jana Koublová
Manager of Monitoring
Bayer s.r.o.
Siemensova 2717/4
155 00 Praha 5



May 6th, 2022



"The Vestra Clinic was the first active site in our biomarker study in Alzheimer's patients, and enrolled our first subject into the trial. Our experience with Dr. Pazdera and the Vestra Clinic team has been excellent. They have been very active and enthusiastic about our study, and very caring towards their patients. We are now starting a new study at the Vestra Clinic, our Phase 3 Alzheimer's study with a specific (APOE4/4) genotype, the APOLLOE4 trial, and they approach it with the same vigor. They are a pleasure to work with".

Sincerely,

Susan Abushakra MD
Chief Medical Officer
Alzheon Inc.



"I have been very impressed with the quality of data generated by Vestra Clinics under the direction of Dr. Pazdera. As a top enroller, Dr. Pazdera did exactly what he promised when he was recruited to participate in our study. This site is highly recommended and we look forward to working with them in the future."

David Brazier
Vice President, Clinical Operations
AZTherapies Inc.
200 Clarendon St, 17th Floor
Boston, MA 02116

Pharmatrophix



May 2022

This letter acknowledges the participation of Vestra Clinics in the Phase 2a randomized controlled trial of LM11A-31-BHS in mild to moderate Alzheimer's disease subjects sponsored by Pharmatrophix in partnership with NeuroScios. Dr. Ladislav Pazdera served as the site Principle Investigator.

Subjects for the overall trial were enrolled at 18 sites located in five countries in the EU. Dr. Pazdera and his team were one of the two highest enrolling sites and randomized the first two subjects in the trial. The team successfully screened 39 subjects and 26 were randomized. Communications were timely and efficient; timelines were met and audits found no critical or major findings.

It was a pleasure to collaborate with Dr. Pazdera and his team.

Frank M. Longo

Pharmatrophix, Menlo Park CA, USA

Nikola Helmberg

NeuroScios, Graz, Austria



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03.03.2022 No. 06/390

Vestra Clinics, s.r.o.
Jiraskova 1389
516 01 Rychnov nad Kneznou,
Czech Republic

Re: Acknowledgement of participation in phase III Clinical Trial No.: OF_NEIR_CT1

This is to confirm the participation of Vestra Clinics, s.r.o., Rychnov nad Kneznou, Czech Republic, in clinical study sponsored by JSC Olainfarm in patients with lumbosacral radiculopathy.

The study began under supervision of the Principal Investigator Dr. Ladislav Pazdera, later led by the Principal Investigator Dr. Oldřich Vyšata.

The study site reached agreed enrolment milestones and quickly become a top enroller among more than 30 sites in Europe. Vestra Clinic's team is professional and dedicated to our study, and the site has gave important contribution in the study accomplishment globally.

Gita Siliga 
Director Medical Affairs and Clinical Research

JSC Olainfarm
5 Rupnicu street, Olaine, LV-2114, Latvia





June 19th, 2019

This memo is to confirm the participation of Vestra Clinics in the FOCUS study of Teva Pharmaceuticals Evaluating the Efficacy and Safety of Fremanezumab for the Prophylactic Treatment of Migraine in Patients with Inadequate Response to Prior Preventive Treatments. Principal Investigator was Dr. Ladislav Pazdera.

Dr. Pazdera and his team were the highest enrolling site of the study globally, out of 112 clinical sites. The team successfully screened 43 patients for participation in the study and randomized 31 patients.

A total of 112 sites screened 1028 subjects and enrolled 838 subjects globally. Dr. Pazdera site met all study timeline and was significant contributor to the study.

Melissa Grozinski-Wolff
Director, Global Clinical Project Management
Teva Branded Pharmaceutical
Products R&D, Inc.
41 Moores Road
Frazer, Pennsylvania 19355
USA



March 6th, 2018

This memo will confirm the participation of Vestra Clinics sro in Axovant's MINDSET study that compared RVT-101 35 mg to placebo in patients with mild to moderate Alzheimer's disease. The Principal Investigator was Dr. Ladislav Pazdera.

Dr. Pazdera and his team were the highest enrolling site of the five sites in the Czech Republic, the 2nd highest enrolling site in the EU, and the 3rd highest enrolling site in the study globally. The team successfully screened 31 patients for participation in the study, and randomized 27 patients. This represented 40% of all patients screened in the Czech Republic, and 47% of all patients randomized in the country. Dr. Pazdera had a very low screen failure rate of only 13%, and all randomized patients completed the trial, compared to a nearly 40% screenfail rate overall.

A total of 177 sites screened 2173 patients and enrolled 1315 patients in 19 countries around the world. Dr. Pazdera's site met all timelines, and was a significant contributor to the study. He was audited by Axovant, and had no critical and no major findings.

Shari Coslett
Vice President Clinical Operations
Axovant Sciences Inc.
11 Times Square, 33rd Floor
New York, NY 10036

The Recruitment Success Story

This leads to robust, powerful, efficient, fast, predictable and accountable delivery that contributes to the completion of clinical trials in a cost-effective and timely manner.

- We carefully **pre-screen the patient population**
- For each clinical trial, **enrollment is launched proactively and simultaneously**, with the momentum sustained until all eligible patients are screened
- The first patient is typically **screened immediately after the initiation visit**
- We engage a **full-time Recruitment and Start-Up Consultant**
- We **maintain the database, network** with >80 cooperating healthcare professionals and institutions, and **educate** physicians, patients and their families as well as developing **marketing** plans
- We conduct **Educational Seminars**, run a proprietary **Memory Clinic, Cognitive Rehab Center, Epilepsy Clinic** and **Migraine Clinic**
- We **advertise** in newspapers, social media and in radio broadcasts via skilled and successful marketers

Diagnosis	Sponsor	Ph	Targetted Number of Patients	Randomized	Target No Delivered	Special Achievement
Success Stories						
Alzheimer's Disease	Alzheon	2	7	8	114 %	First patient randomized / first dosed in the World
Alzheimer's Disease	AZTherapies, Inc.	3	30	31	103 %	Rescue center, first 9 succesfull screened patients in 5 weeks
Neuropathic pain	Bayer AG	2	10	15	150 %	The first patient enrolled first in the world
Radiculopathy pain	Biomapas	3	12	16	133 %	First patient screened, randomized, dozed, randomization still ongoing
Alzheimer's Disease	Frank Longo PharmatropiX	2	8	26	325 %	First 2 patients randomization / dozed in the World
Parkinson's Disease	Merck & Co.	3	10	14	140 %	Best in Europe in Treatment Naive Patients
Spasticity	Merz Pharmaceutical GmbH	3	25	28	112 %	First 28 successful screened patients in 20 weeks
Migraine	Teva Pharmaceutical Industries, Ltd.	3	12	31	258 %	First 43 screened patients in 10 weeks
Pain, spondylarthritis	UCB BIOSCIENCES GmbH	3	3	5	167 %	Fastest enrollment in 6 weeks as a rescue site

Sponsors and CRO Partners in clinical trials

Acadia Pharmaceuticals

Accelsiors

Acorda Therapeutics

Allergan

Amgen

Angelini

Adagio Therapeutics Inc.

Apodemus

Astellas

Avanir Pharmaceuticals

Axovant Sciences

AZTherapies

Bayer AG

BenevolentAI Bio

Bial-Portela

Biomapas

Biotie Therapies

Boehringer Ingelheim

Bristol-Myers Squibb

Cerevel Therapeutics

Chiltern International

Cortexyme

Covance

Daiichi Sankyo

EastHORN Clinical Services

EIP Pharma

Eisai Medical Research

Estetra

Forum Pharmaceuticals

GlaxoSmithKline

GW Research

Laboratorios Lesvi, S.L.

Lundbeck

H. Lunbeck A/S

Heptares Therapeutics

Hoffman La-Roche

ICON Clinical Research

Institut Dr. Schauerte

Iqvia

Janssen-Cilag

Julius Clinical

Linical

Lupin

Merck & Co

Merz Pharmaceutical

Mundipharma Research

Neox Clinical Research

Neurocrine Biosciences

NeuroDerm

Neuroscios

Novartis

Omnicare Clinical Research

NSC Therapeutics

Orion Pharma

PAREXEL

Peter Sandercock

Pfizer

Pharmaceutical Product Development

Pharmatrophix

PRA Health Services

Purdue Pharma

Regeneron Pharmaceuticals Inc

Revance Therapeutics Inc

Scope International

Selecta Biosciences

Servier Institute de Recherches

SK Biopharmaceuticals

Sunovion

Syneos

Teva Pharmaceutical Industries

TFS International

Theravance

Toyama

UCB

VU University

Alzheimer Center Amsterdam

Western General Hospital Edinburgh

Worldwide Clinical Trials

World Leader in Patient Recruitment

Our recruitment methods are professionally geared towards the given patient population, so we can aim for much higher enrollment numbers. Hence, we are frequently ranked as the best recruiters.

- Conducted almost **100** phase II and III RCTs
- Enrolled more than **600** patients

At the moment, we have completed approximately 100 clinical evaluations, out of which:

- 35 clinical trials were for Alzheimer's disease,
- 17 clinical trials for Epilepsy,
- 17 studies for Parkinson's disease,
- 8 studies for Diabetic neuropathy,
- 9 were Migraine clinical trials.

Other indications included Multiple Sclerosis, Stroke, Radiculopathy and Back pain, Spasticity, Torticollis and others.

Protocol No	Eudra-CT No	NCT	Diagnosis	Sponsor / Investigator Initiated	Ph	Active compound	Targeted Number of Patients	Screened	Randomized	Target No Delivered	Special Achievement
Top 3 in the World in Recruitment											
RVT-101-3001	2015-002957-37	NCT02585934	Alzheimer's Disease	Axovant Sciences Ltd.	3	intepirdine	20	31	27	135 %	Rescue center, first 9 successful screened patients in 5 weeks
AZT-001	2015-002147-34	NCT02547818	Alzheimer's Disease	AZTherapies, Inc.	3	Ibuprofen/sodium cromoglicate	30	78	31	103 %	
12936A	2009-011845-24	NCT01019421	Alzheimer's Disease	H. Lundbeck A/S	2	idalopirdin	12	31	20	167 %	
14861A	2012-004763-45	NCT01955161	Alzheimer's Disease	H. Lundbeck A/S	3	idalopirdin	17	30	20	118 %	First 2 patients randomization / dozed in the World
NSC15001	2015-005263-16	NCT03069014	Alzheimer's Disease	Frank Longo Pharmatrophix	2	LM11A-31	8	39	26	325 %	
BIA-2093-311	2009-011135-13	NCT01162460	Epilepsy	Bial-Portela & Ca, S.A.	3	eslicarbazepin	10	14	14	140 %	First 43 screened patients in 10 weeks
BIA-2093-311/EXT	2015-001243-36	NCT02484001	Epilepsy	Bial-Portela & Ca, S.A.	3	eslicarbazepin	5	5	5	100 %	
093-046	2010-018684-42	NCT01091662	Epilepsy	Sunovion Pharmaceuticals Inc.	3	eslicarbazepin	7	21	13	186 %	
093-050	2010-19000-22	NCT00910247	Epilepsy	Sunovion Pharmaceuticals Inc.	2	eslicarbazepin	7	10	10	143 %	The first patient enrolled first in the world
GWEP1330 B	2014-002594-11	NCT02365610	Epilepsy	GW Research Ltd.	2	cannabidivarin	6	9	6	100 %	
TV48125-CNS-30068	2017-002441-30	NCT03308968	Migraine	Teva Pharmaceutical Industries, Ltd.	3	fremanezumab	12	43	31	258 %	First patient screened, randomized, dozed, randomization still ongoing
BAY 1817080	2020-002066-14		Neuropathic pain	Bayer AG	2	P2X3 antagonist	10	19	15	150 %	
8477-CL-0020	2013-002521-27	NCT02065349	Neuropathic pain	Astellas Pharma Europe B.V.	2	quetenza	10	16	13	130 %	First 28 successful screened patients in 20 weeks
E05-CL-3002	2009-016458-42	NCT01478607	Neuropathic pain	Astellas Pharma Europe B.V.	3	Qutenza®	15	29	23	153 %	
OF_NEIR_CTI	2019-002632-90	-	Radiculopathy pain	Biomapas	3	neiromidine	12	16	16	133 %	Fastest enrollment in 6 weeks as a rescue site
MRZ 60201/SP/3001	2010-023043-15	NCT01392300	Spasticity	Merz Pharmaceutical GmbH	3	botulotoxin	25	28	28	112 %	
MRZ 60201/SP/3002	2010-024579-23	NCT01464307	Spasticity	Merz Pharmaceutical GmbH	3	botulotoxin	20	25	21	105 %	
Top 3 in Europe / Home in Recruitment											
CL2-38093-011	2010-024626-37	-	Alzheimer's Disease	Servier, Institut de Recherches International	2	S38093	20	32	15	75 %	Best in Europe in Treatment Naive Patients
EVP-6124-025	2013-002653-30	NCT01969136	Alzheimer's Disease	Forum Pharmaceuticals, Inc.	3	encenicline	8	14	10	125 %	
ALZ-801-201ADBM	2020-000986-17	NCT04693520	Alzheimer's Disease	Alzheon	2	tramiprosate / homotaurine	7	25	8	114 %	
GWEP1330 A	2014-002594-11	NCT02369471	Epilepsy	GW Research Ltd.	2	cannabidivarin	3	2	2	67 %	Fastest enrollment in 6 weeks as a rescue site
GWEP1330 B	2014-002594-11	NCT02365610	Epilepsy	GW Research Ltd.	2	cannabidivarin	6	9	6	100 %	
DS5565-A-E309	2013-005161-40	NCT02146430	Pain, fibromyalgia	Daiichi Sankyo Development Ltd.	3	mirogabalin	10	19	11	110 %	
AS0006	2015-001894-41	NCT02552212	Pain, spondylarthritis	UCB BIOSCIENCES GmbH	3	certolizumab	3	15	5	167 %	Best in Europe in Treatment Naive Patients
P05664	2009-015161-13	NCT01155479	Parkinson's Disease	Merck & Co.	3	preladenant	10	18	14	140 %	
P05664	2009-015161-13	NCT01155479	Parkinson's Disease	Merck & Co.	3	preladenant	10	18	14	140 %	

Dedicated Team of Experts

Vestra Clinics has gained over 12 years of clinical research experience since our dedicated research facility opened in 2008. Company comprises a **professional team of research enthusiasts**, including fully board licensed therapeutic area investigators. **The study site is managed** by skilled clinical coordinators **Hana Horáková, Eva Slívová Rolečková** and **Veronika Witczaková** along with a core team of experienced clinical research professionals, clinical research nurse and coordinators, most of whom have a background in medicine and/or biosciences. Members of our team have held teaching positions and/or successfully directed medical and informatics operations. These include recruitment specialist, nurses, investigators, sub-investigators, clinical coordinators, raters, administrators. Our full-time Recruitment/Start-up Consultant, **Dáša Kudláčková** and her team implements streamlined processes for effectively enrolling patients in compliance with local and international legal, regulatory and ethical requirements. Psychological testing is performed by Mrs. **Ekaterina Zaporojan**.

The owner and CEO of Vestra Clinics, **Ladislav Pazdera**, MD, FAAN, has acted as the principal investigator in more than 50 industry-sponsored clinical trials and is an established key opinion leader for a number of Sponsors/CROs.

Vestra Clinics has an Expert Advisor, Dr Joris J. de Bie, MBS, PhD, who is also Executive Director for Global Clinical Operations Global Head of Study Management at Chugai Pharmaceutical Co., Ltd, USA. Dr de Bie brings his vast experience in building and leading clinical operations groups to our research facility.

Our Recruitment / Start-Up Consultant drives recruitment via various activities:



Clinical Trial Benchmarks

Benchmark	Time
IRB Submission ▼ Approval	2 weeks
Median Time to First Consent	1 week
Protocol Review And Monitoring Committee Application Submitted ▼ Approval / Open to Enrollment	2 weeks
Contract Draft Received ▼ Contract Executed	2 weeks
Budget Draft Received ▼ Budget Finalized	2 weeks
Contract Executed ▼ Open to Enrollment	1 week
Open to Enrollment ▼ First Patient In	2 weeks

WE ...

...deliver optimal clinical trials solutions, **FAST**.

...**ARE A WORLD LEADER** in patient recruitment,
ranking first in global clinical trials.

...offer a comprehensive service from a dedicated
and experienced **PROFESSIONAL TEAM**.

...cover a broad **RANGE OF THERAPEUTIC** areas.

...establish **STRONG AND PRODUCTIVE**
RELATIONSHIPS with Sponsors and CROs.

Delivering Optimal Clinical Research

We provide a high-quality, flexible service to ensure clinical trials are conducted as efficiently as possible.

Preparation and Partnership	Advance trial planning via personal, close cooperation with the Sponsor/CRO, allowing efficiency from initiation to completion
	Rapid clinical trial agreement and budget review , avoiding delays in trial initiation
	Identifying experienced investigators: therapeutic area specialists, research enthusiasts and good communicators with the Sponsor/CRO, with accountability for every step of the trial
	Responsible for contract negotiation and reimbursement of investigators and other personnel within the agreed budget
Patient Focus	Access to a population of 6 thousand preselected and prescreened patients , enabling excellent recruitment and retention
	Fast monophasic recruitment of large numbers of suitable patients, selected with the utmost care
	Patient-led approach aimed at securing their attention and cooperation by focusing on respect, clear information, comfort, emotional support and continuity for patients and their families
Operational Excellence	Full accountability in every part of every clinical trial
	Efficient and timely monitoring for the trial CRA
	No rework due to high compliance to the trial protocol
	Stringent internal processes to ensure data quality, financial management and ethical standards are maintained
	Close monitoring of trial performance to proactively mitigate risk and instigate preventive measures
	Full time recruitment and start up consultant is employed
	Skilled QA personnel are members of the team
Regulatory Compliance	Strict adherence to regulatory requirements for clinical trial conduct including ICH-GCP, FDA, EMA, and local regulations
	Facilitating the preparation of regulatory submissions with the Sponsor/CRO
	Recognised as a highly specialised center (third tier level) for the diagnosis and treatment of dementia by the State Institute for Drug Control (SÚKL)

Broad Therapeutic Area Expertise

Vestra Clinics can assist with clinical trials in many therapeutic areas, specializing in Central Nervous System plus Dermatology disorders. Vestra Clinics runs memory and cognitive rehab clinics for dementia patients, as well as clinics for epilepsy and migraine patients. For example, we have conducted 26 clinical trials in alzheimers disease (13 each in phase II and III, respectively)

State Institute for Drug Control (SÚKL) recently recognised Vestra Clinics as a highly specialized center (third-tier level) for the diagnosis and treatment of dementia that can indicate for amyloid PET scan referrals.

Stroke and Cardiovascular diseases

Migraine

Neurodegenerative diseases

including all dementia syndromes, Parkinsonism, Alzheimer's disease and mild cognitive impairment and other neurological disorders

Psoriasis and other cutaneous disorders

Pain syndromes

including osteoarthritis and low back pain

Epilepsy

We pride ourselves in establishing strong, long-lasting and productive relationships with Sponsors and CROs, based on mutual trust and cooperation.

**For more information
on partnering with us,
please get in touch**



Vestra Clinics s.r.o.

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