

1. DACH ANCA VASKULITIS FORUM 2023
12. & 13. MAI 2023

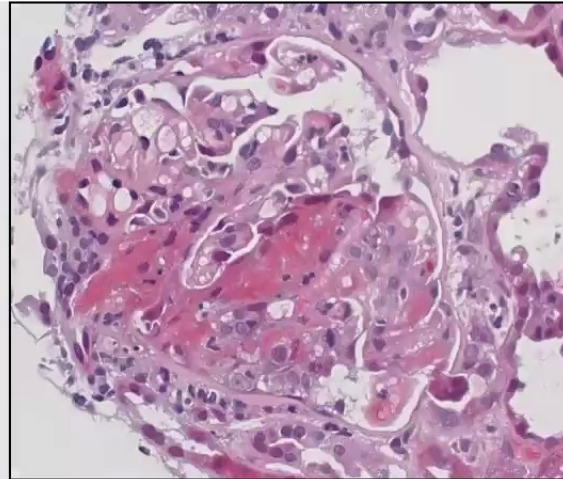
AAV Experten-Zentren
stellen sich vor:
Charité - Universitätsmedizin Berlin

Priv.-Doz. Dr. Adrian Schreiber
Dr. Udo Schneider



Berlin





1 Medizinische Klinik mit
Schwerpunkt Nephrologie und
Internistische Intensivmedizin

2 Medizinische Klinik mit
Schwerpunkt Rheumatologie
und Klinische Immunologie

Charité - Universitätsmedizin
Berlin

Vasculitis Center Charité

Adrian Schreiber¹ & Udo Schneider²

Interessenskonflikte

Udo Schneider

Amgen
Astra Zeneca
BMS
Boehringer Ingelheim
Galapagos
GSK
Roche
Sobi
Vifor

Adrian Schreiber

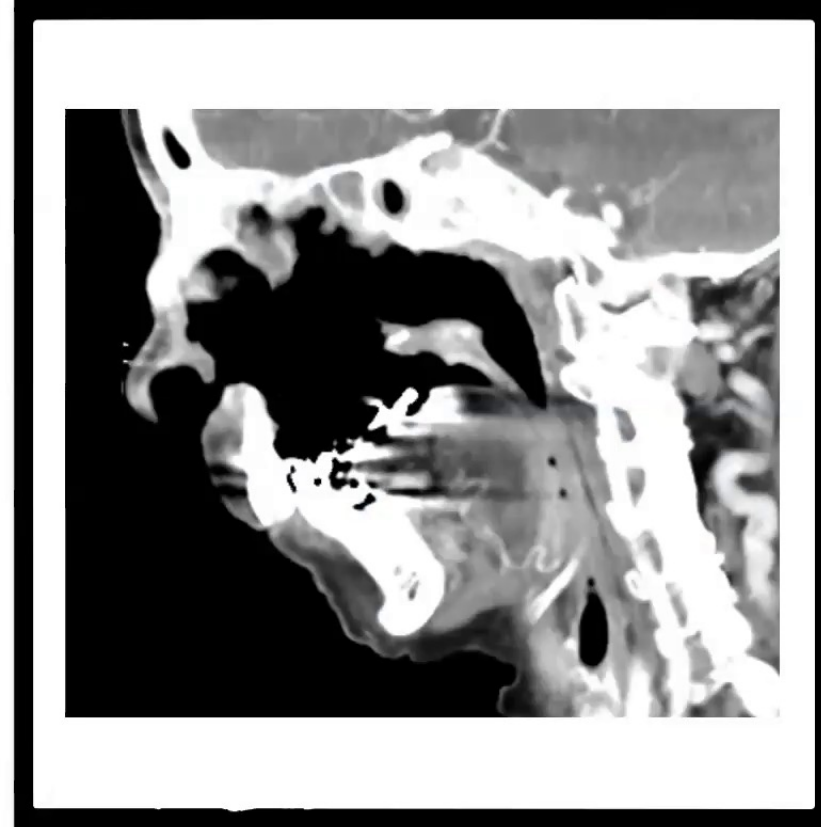
Vifor
GSK
Sanofi
Otsuka
Stadapharm
Alexion
Hansa Biopharm

„Cases are
not
science...”



„Cases are not
science...“,
neither are
cases fiction

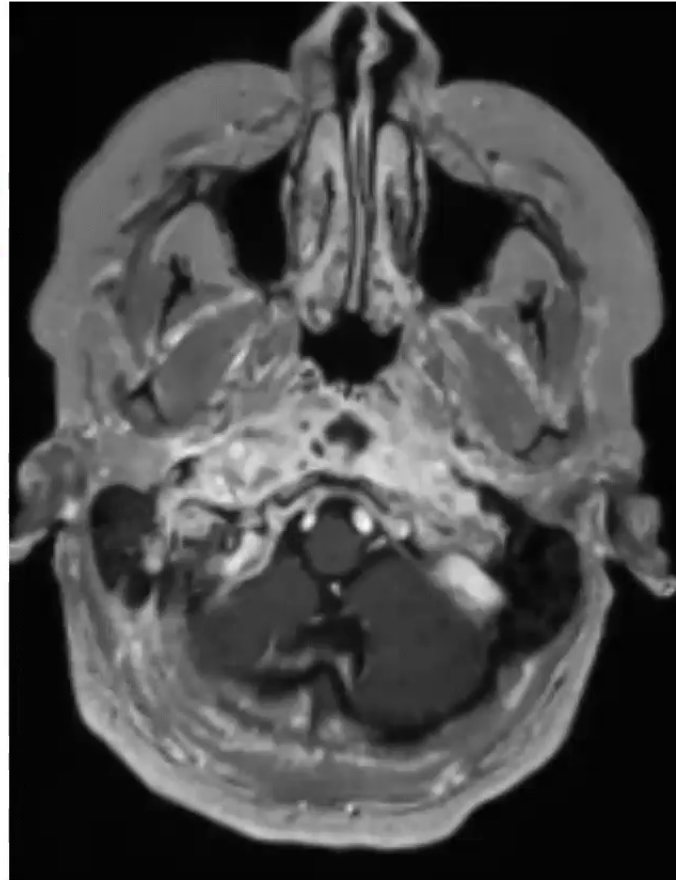




**ED GPA, f, 82 J.: komplette
Gaumendestruktion in 8W**



f, 58
ED GPA
2022
RTX->Aza



Initiale Therapie der ersten Wochen...

Übernahme

Lufu

Labor

CT

Patho

Verlauf



- Hochdosis Methylprednisolon; dann 1mg/kgKG
- Therapeutischer Plasmaaustausch (FFP)
- Rituximab d1+d7+d21
- Cyclophosphamid i.v. (Kryokonservierung)
- Mehrfache Bronchoskopien bei Verlegung der Bronchien

Initiale Therapie der ersten Wochen...

Übernahme

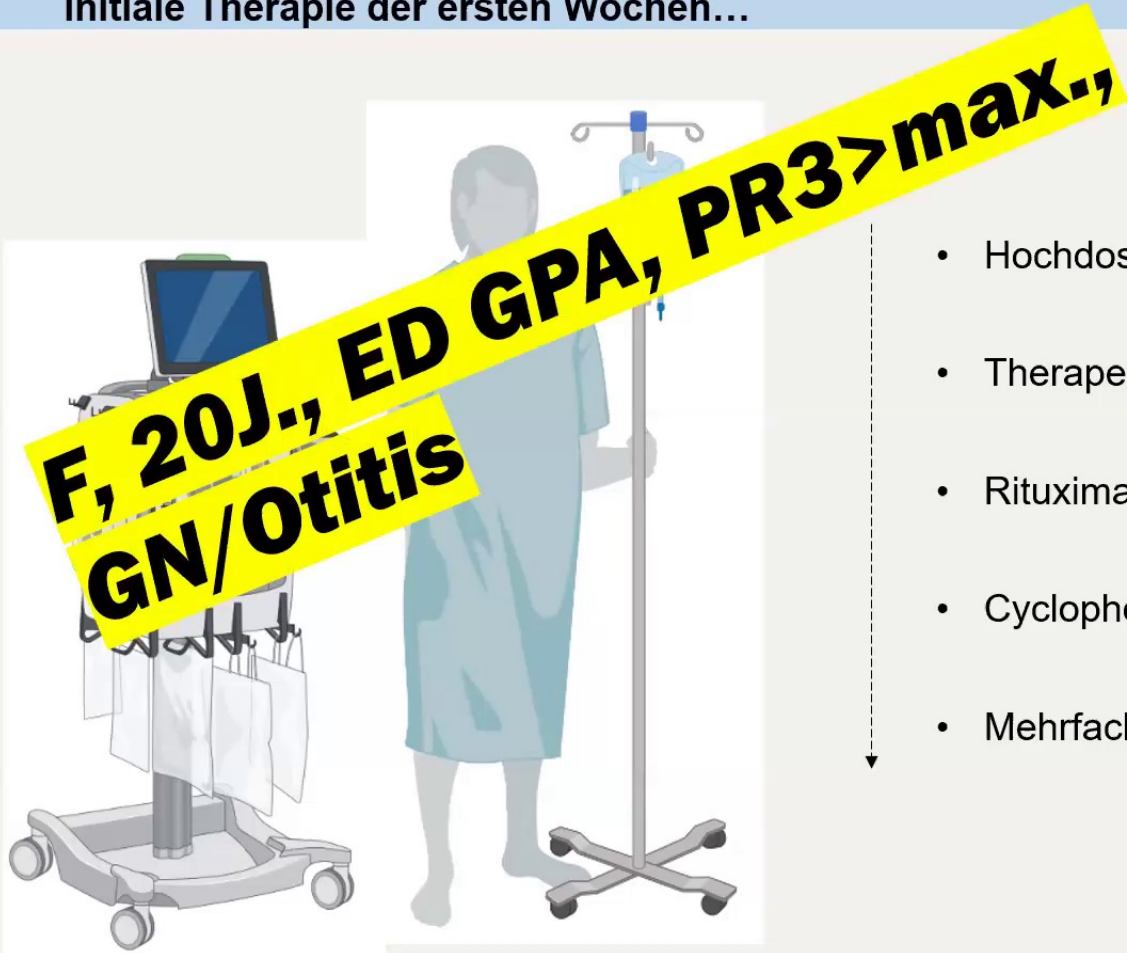
Lufu

Labor

CT

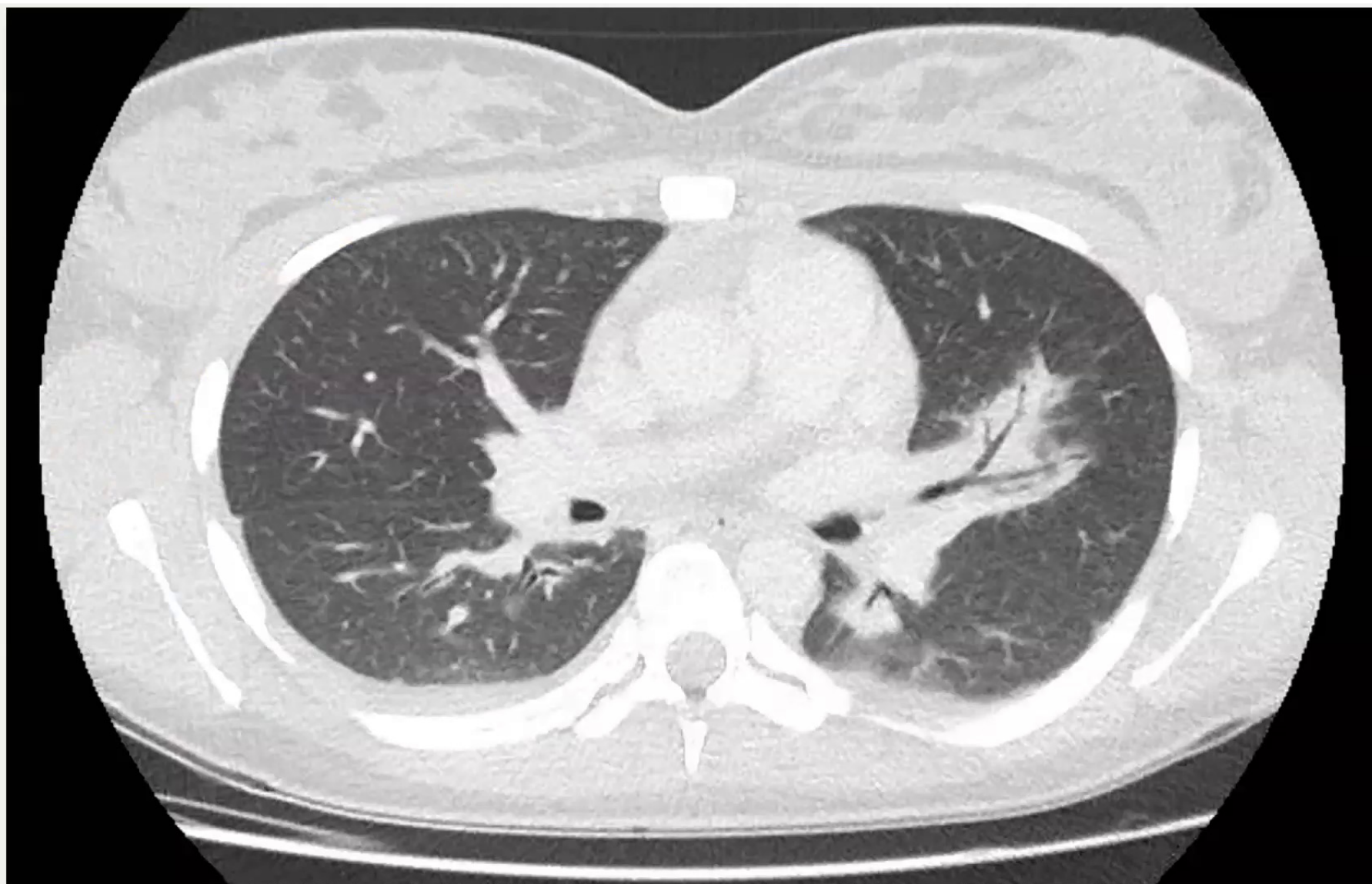
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Bronchoskopie bei 2. Aufnahme

Übernahme

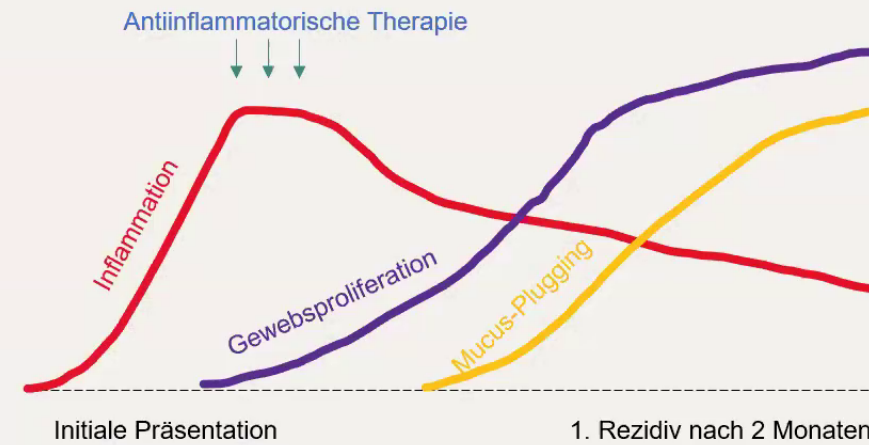
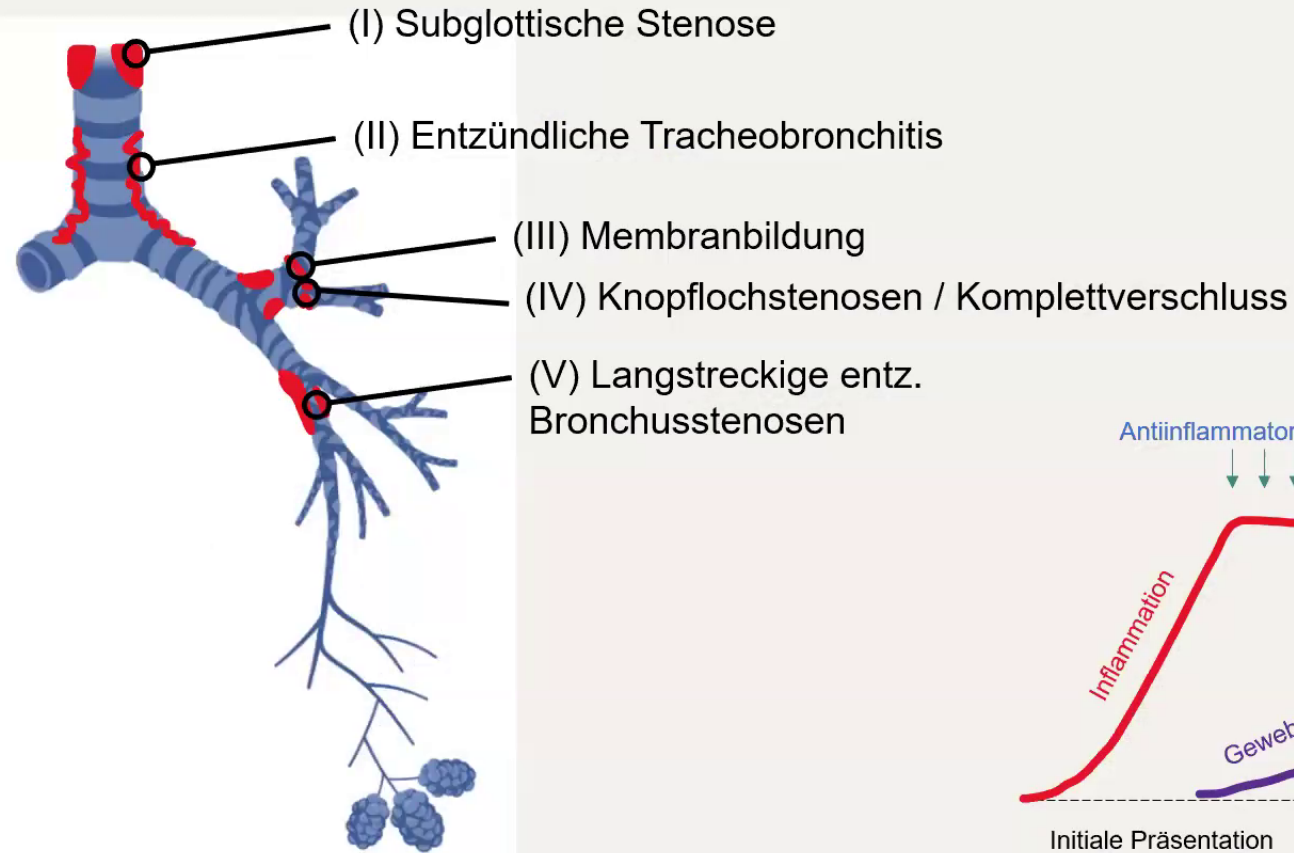
Lufu

Labor

CT

Patho

Verlauf



Bronchoskopie bei 2. Aufnahme

Übernahme

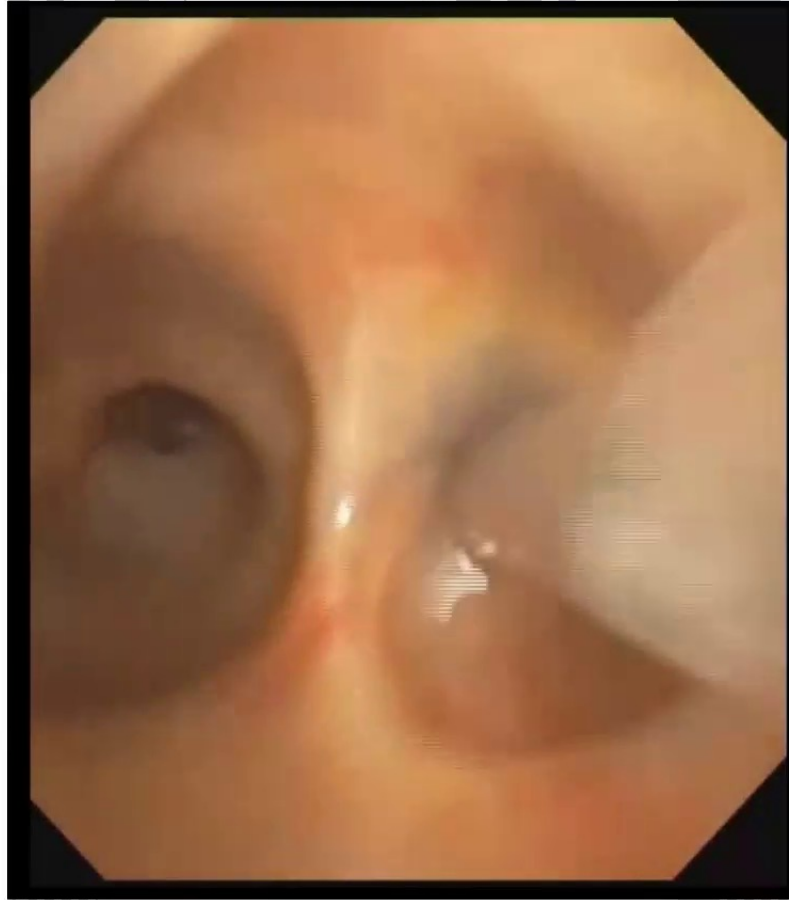
Lufu

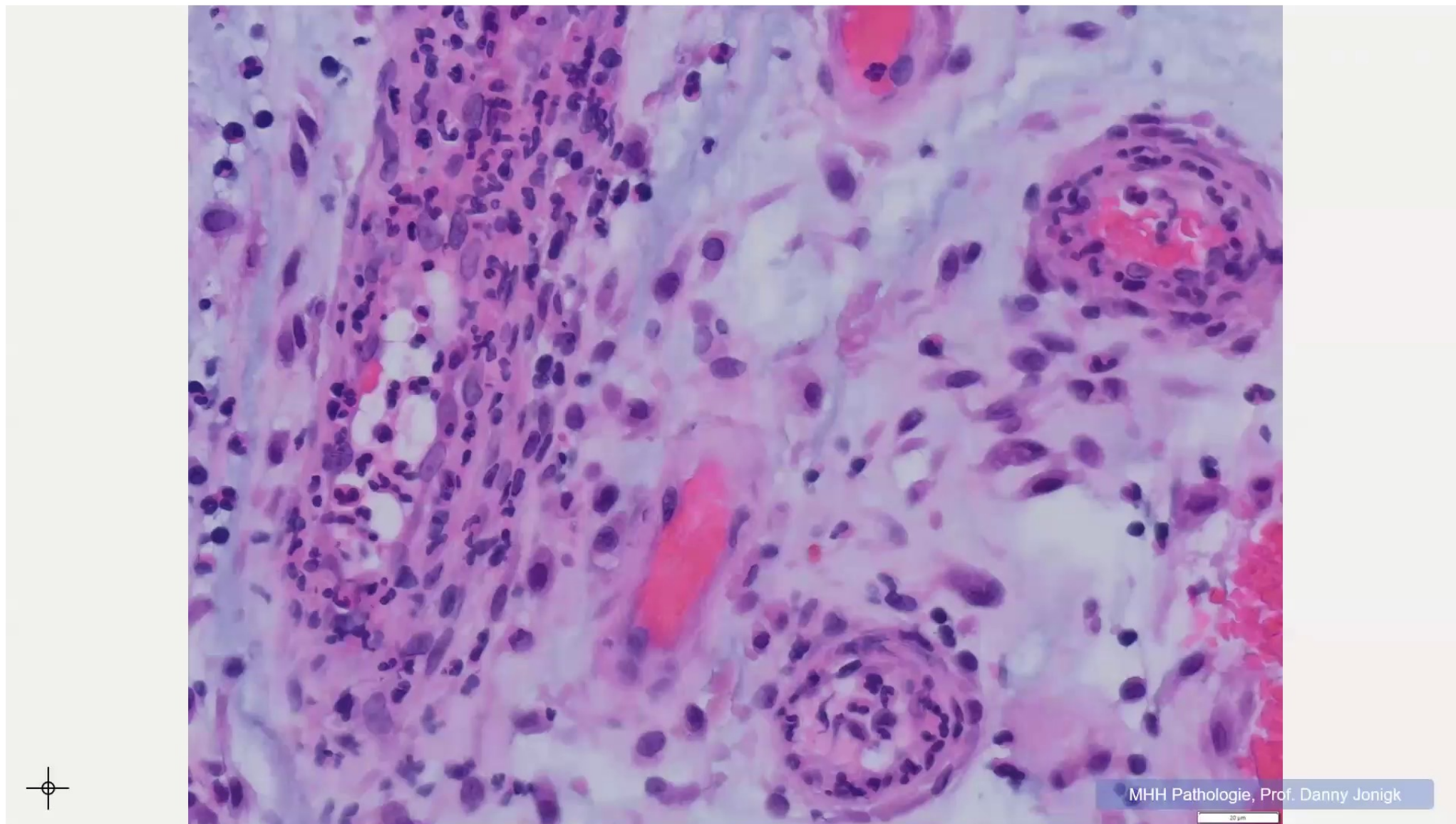
Labor

CT

Endo

Verlauf





m, 77J.,
MPO+



m, 77J.,
MPO+

D: Idiopathische
Hypertrophe
Pachymeningitis

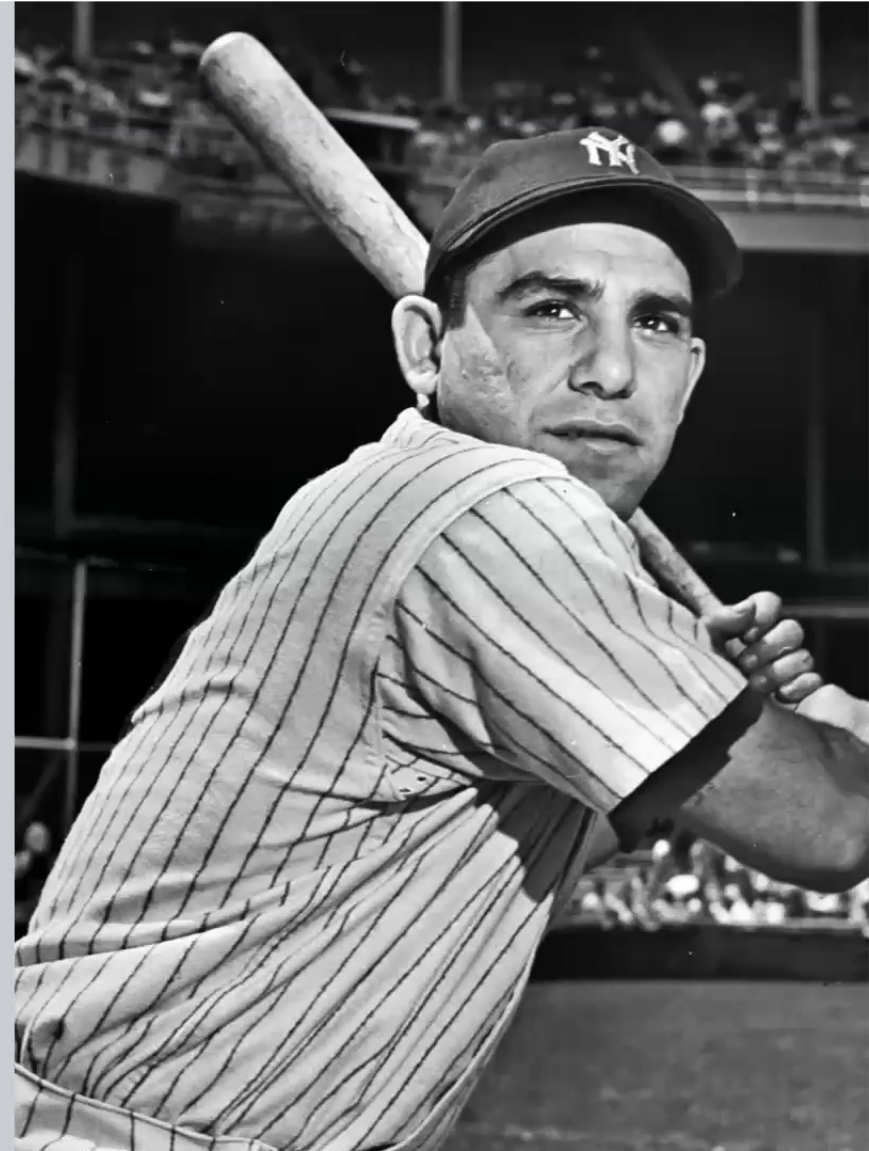


„It's amazing
what you can
see, when you
take a look“

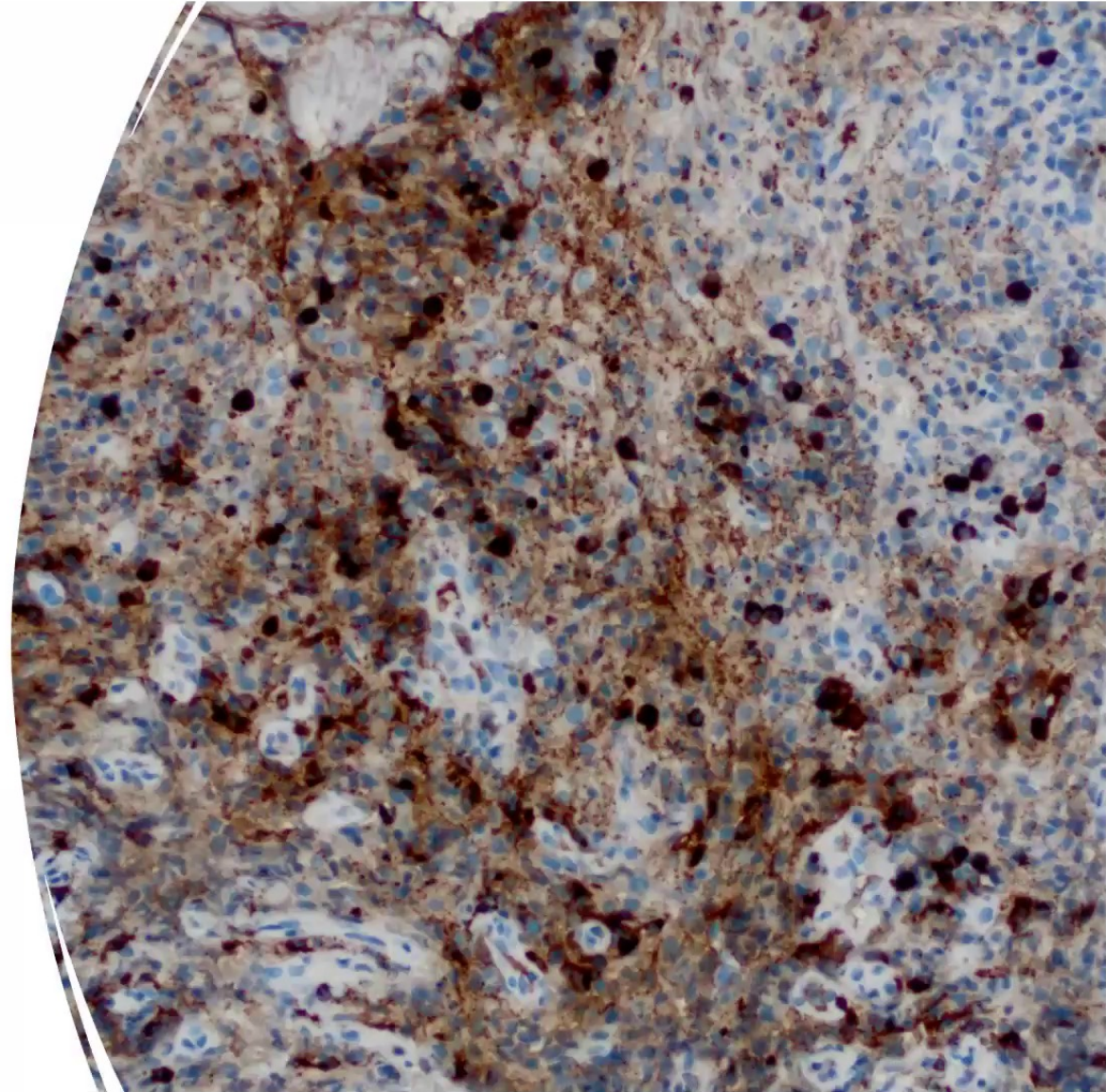
Yogi Berra, 1925–2015



Bildquelle: The New Yorker.



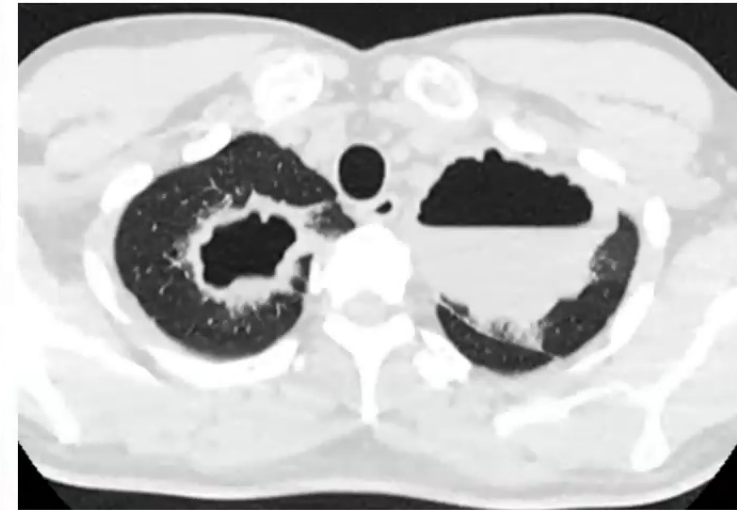
IgG4+:
Biopsie aus
Sinus
cavernosus



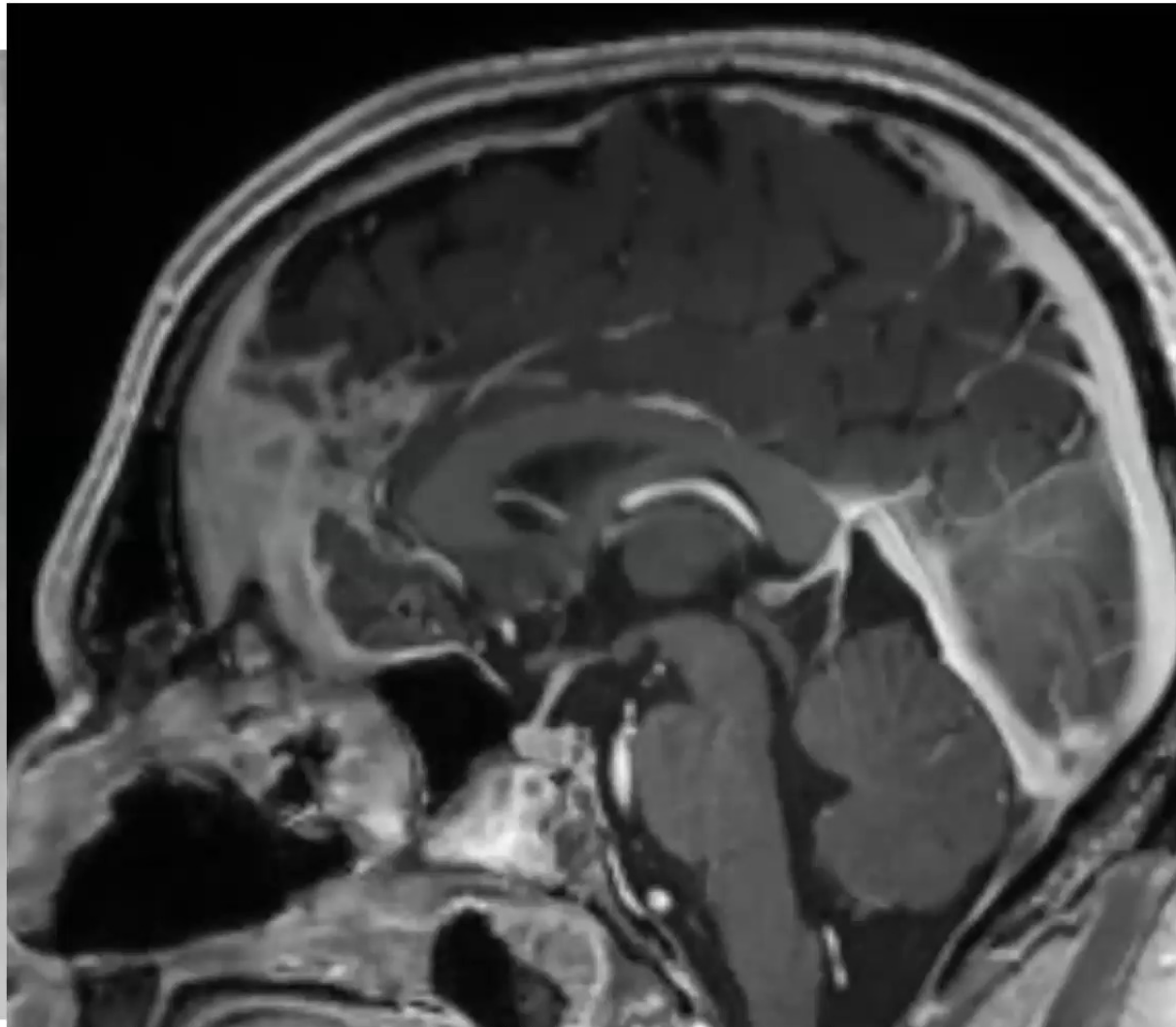
m, 39
ED GPA 2017
Seit 1a wegen
Sinusitis in
HNO-
ärztlicher
Behandlung

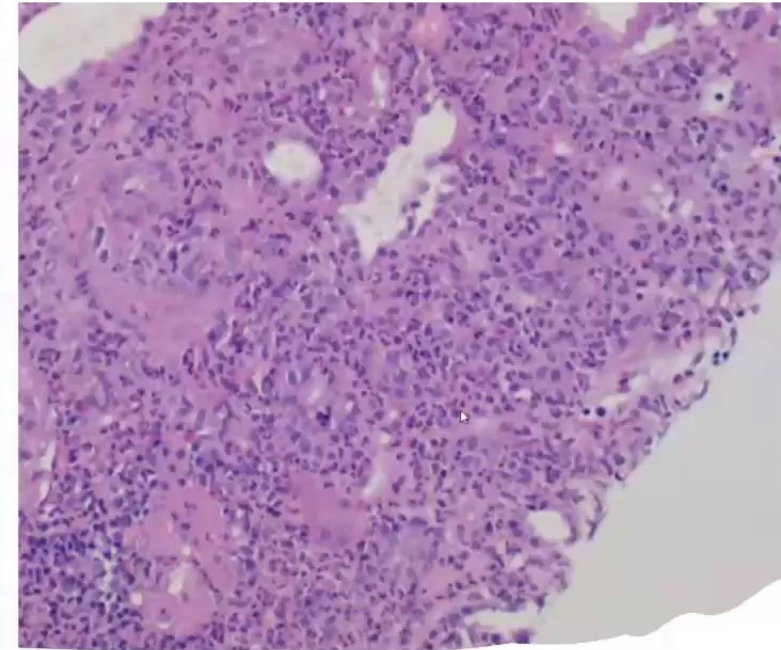
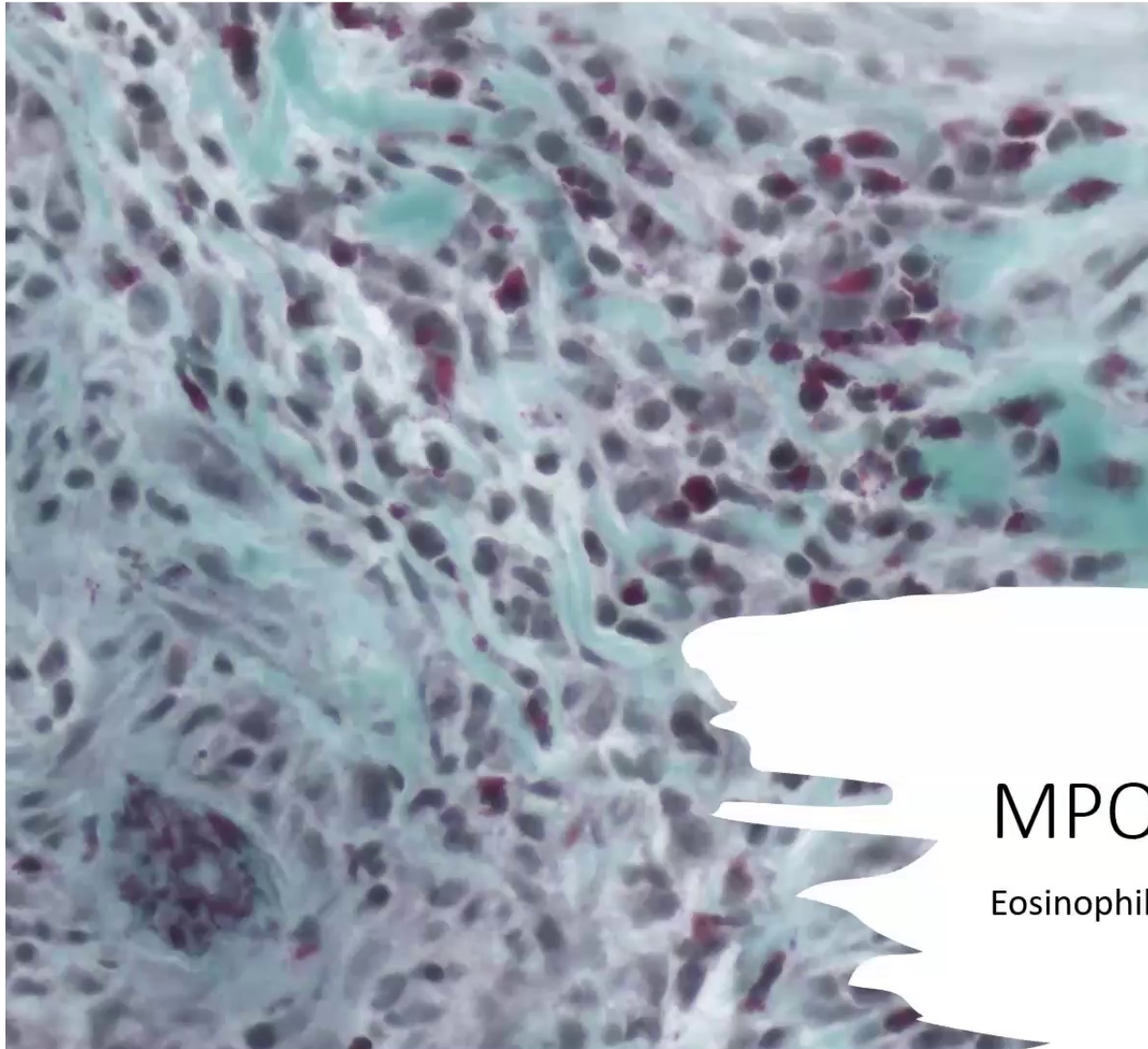


m, 39
ED GPA 2017
Seit 1a wegen
Sinusitis in
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m, 39
ED GPA 2017
Seit 1a wegen
Sinusitis in
HNO-
ärztlicher
Behandlung





MPO+ eGPA

Eosinophiles Infiltrat in Nerv (li.) und Niere (re.)

Zwischenfazit:

interdisziplinäre Versorgung
von AAV-Pat. an Zentren
schon allein aufgrund des
Managements lokaler
Komplikationen +
Histologiegewinnung
sinnvoll



Patientennahe Forschung

Endopeptidase Cleavage of Anti-Glomerular Basement Membrane Antibodies *in vivo* in Severe Kidney Disease: An Open-Label Phase 2a Study

Fredrik Uhlin,^{1,2} Wladimir Szpirt,³ Andreas Kronbichler,⁴ Annette Bruchfeld,^{1,5}
Inga Soveri,⁶ Lionel Rostaing,⁷ Eric Daugas,⁸ Arnaud Lionet,⁹ Nassim Kamar,¹⁰
Cédric Rafat,¹¹ Marek Mysliveček,¹² Vladimír Tesár,¹² Anders Fernström,¹
Christian Kjellman,¹³ Charlotte Elfving,¹³ Stephen McAdoo,¹⁴ Johan Mölne,¹⁵
Ingeborg Bajema,¹⁶ Elisabeth Sonesson,¹³ and Mårten Segelmark,^{1,17}

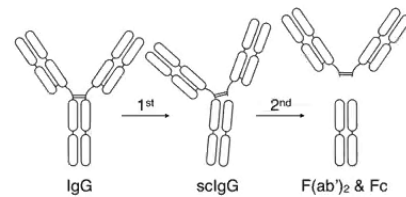
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Imlifidase (Idefirix, Hansa Biopharma)

→ Cystein Protease von *Strep. pyogenes*



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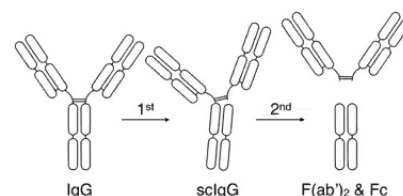


Table 1. Baseline clinical characteristics

Characteristics	Men	Women	All	Historical Controls
Number, n (%)	9 (60)	6 (40)	15 (100)	50 (100)
Country: France/Sweden/Denmark Austria/Czech Republic, n	3/1/2/1/1	2/3/1/0/0	5/4/3/2/1	NA
Age years median (range)	60 (19–77)	66 (32–71)	61 (19–77)	63 (16–88)
ANCA MPO/PR3/none, n (%)	3/2/5 (33/22/56)	1/0/4 (17/0/67)	4/2/9 (27/13/60)	15/7 ^a /29 (30/14/58)
ANA positive, n (%)	3 (33%)	0	3 (20%)	NA
Renal function oliguria/dialysis/no dialysis, n (%)	4/4/1 (44/44/11)	1/1/4 (17/17/67)	5/5/5 (33/33/33)	41 ⁷ /9 (82/18)
Pulmonary disease AH/other/none, n (%) ^b	1/2/6 (11/22/67)	1/2/3 (17/33/50)	2/4/9 (13/27/60)	21/NA/NA (42/NA/NA)
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Platelets 10 ⁹ /L median (range) ^c	318 (131–505)	320 (201–384)	320 (131–505)	NA
Berden class crescentic/mixed/sclerotic/focal, n (%)	6/2/0/0 (75/25/0/0)	3/2/1/0 (50/33/17/0)	9/4/1/0 (65/29/7/0)	25/3/1/0 (86/10/3/0)
Normal glomeruli, % median (range)	11% (0–29)	9% (0–35)	9.5% (0–35)	6.5% (0–43)
Linear staining for IgG, n/n (%)	5/8 (62)	6/6 (100)	11/14 (79)	27/29 (93)

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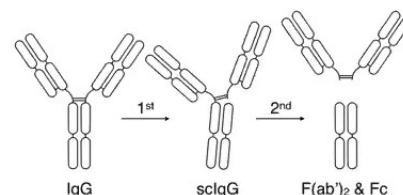
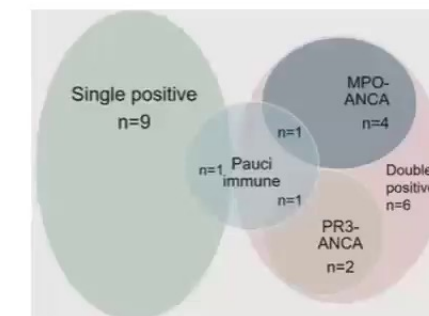


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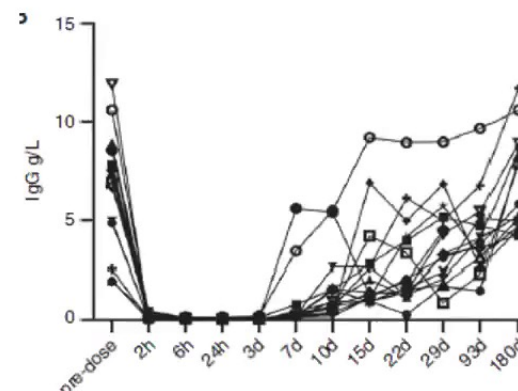
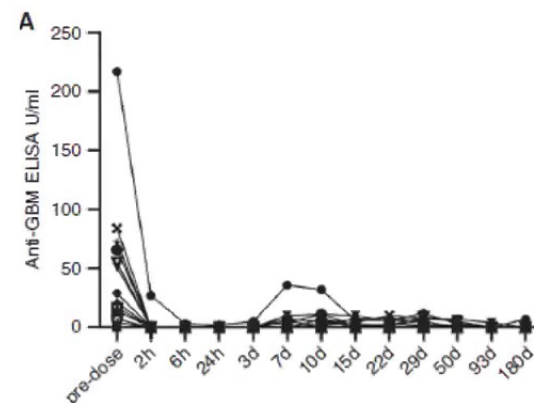
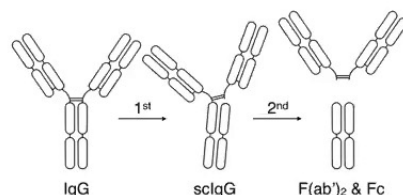
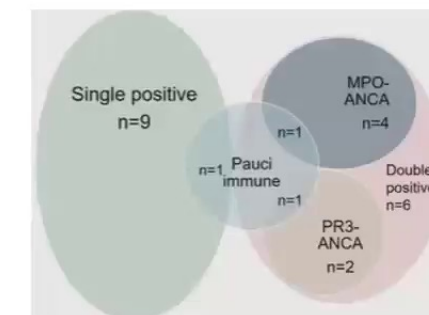


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Patientennahe Forschung



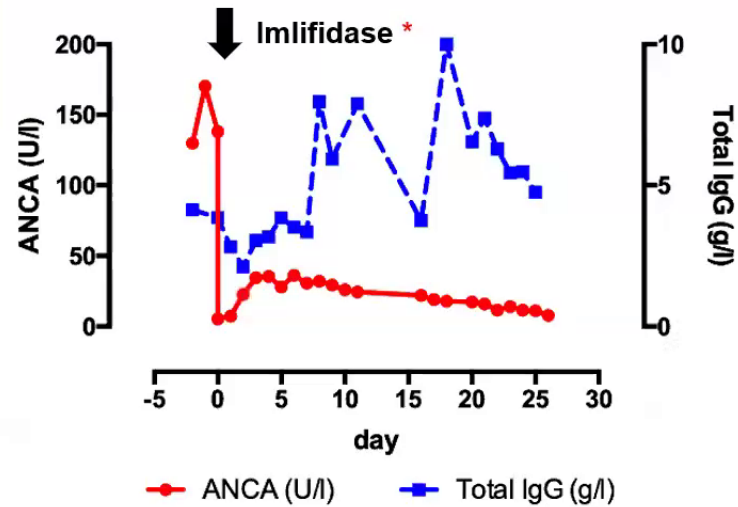
Patientennahe Forschung



Immunsuppression bestehend aus Plex, Steroid, Cyclophosphamid, Rituximab

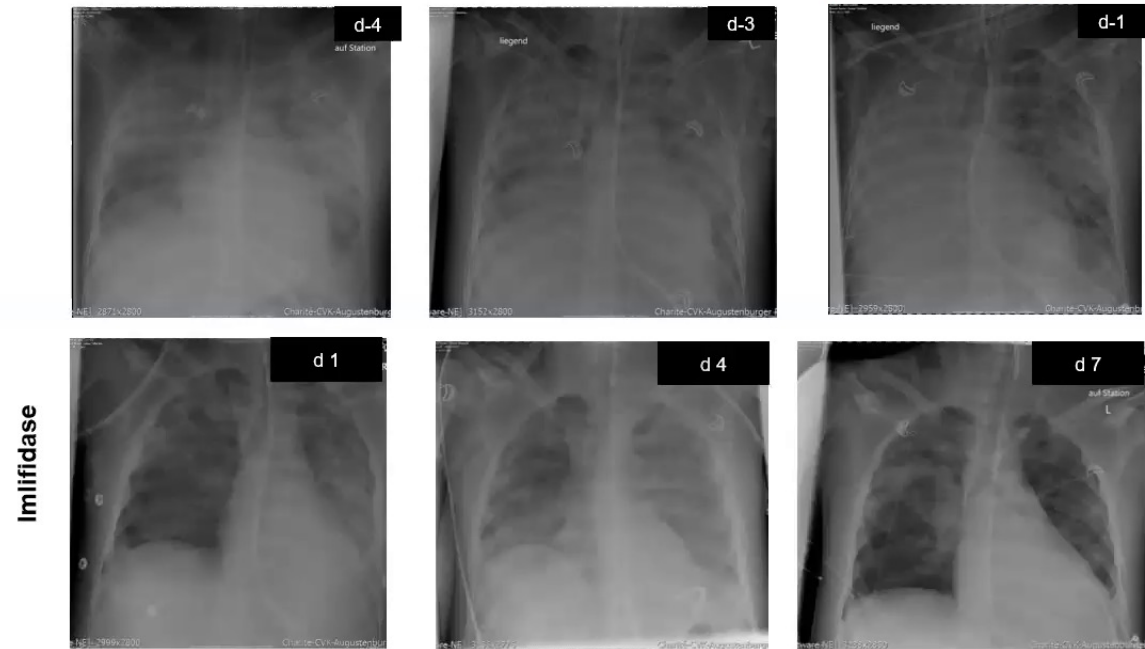
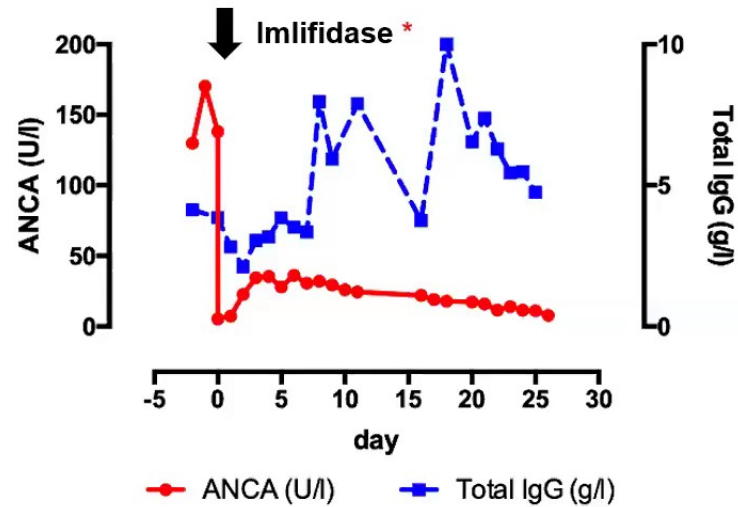
Patientennahe Forschung

* Hinweis: Imlifidase ist nicht zur Therapie von AAV zugelassen



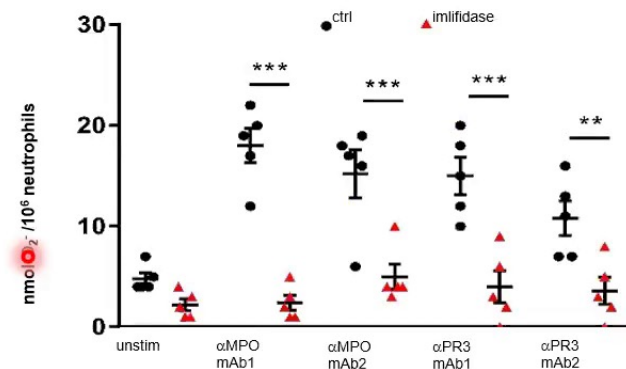
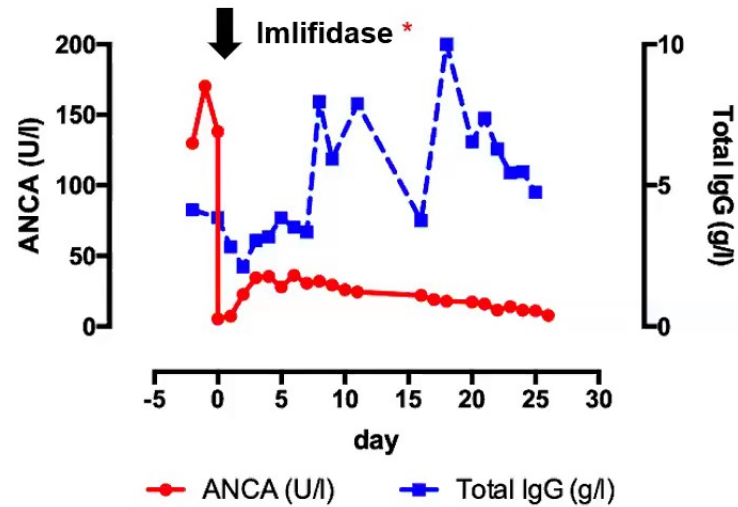
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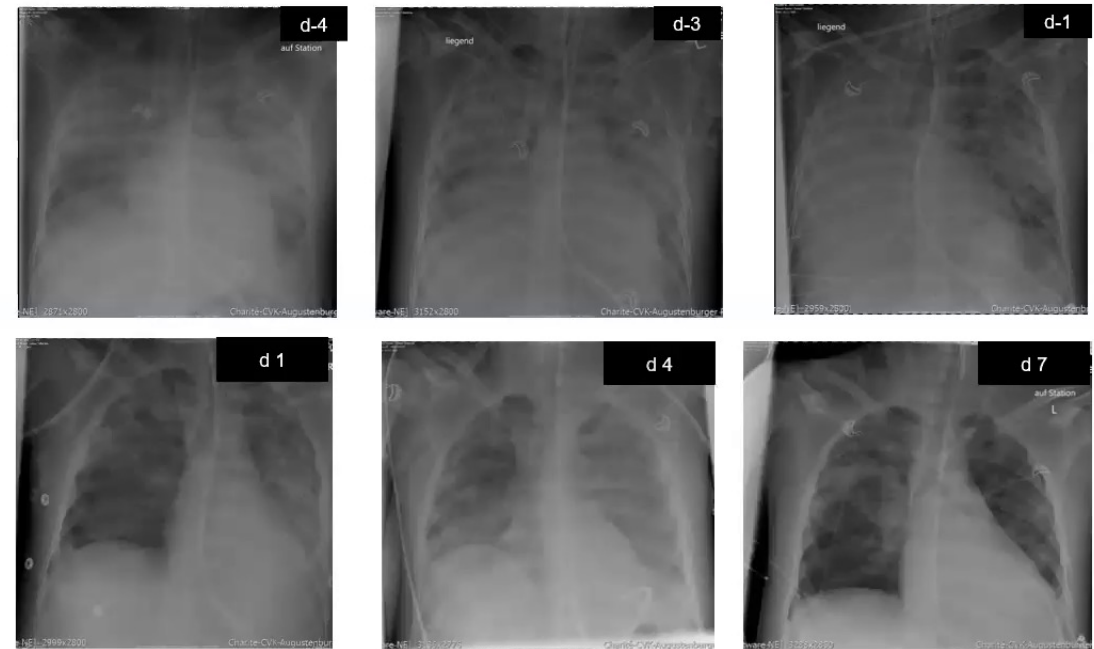


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Imlifidase



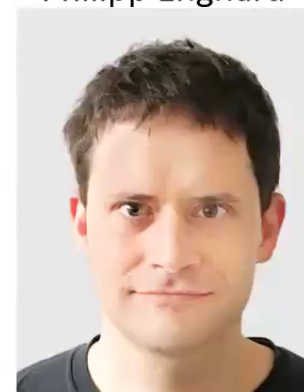
Patientennahe Forschung

Name of Study	Imlifidase in ANCA-associated vasculitis		
Protocol Number:		Phase: Investigator- Sponsored Trial	Country: Germany
Principal Investigator	Adrian Schreiber / Philipp Enghard		
Indication	Severe ANCA associated vasculitis with Acute Respiratory Distress Syndrome due to pulmonary hemorrhage		
Investigational Agent	Imlifidase for injection (Hansa Biopharma AB)		
Study center(s)	Charité – Universitätsmedizin Berlin • Charité Campus Mitte, Charitéplatz 1, 10117 Berlin • Campus Virchow Klinikum, Augustenburger Platz, 13353 Berlin • Campus Benjamin Franklin, <u>Hindenburgdamm</u> 30, 12203 Berlin		
Sample size	10 patients		

Janis Sonnemann

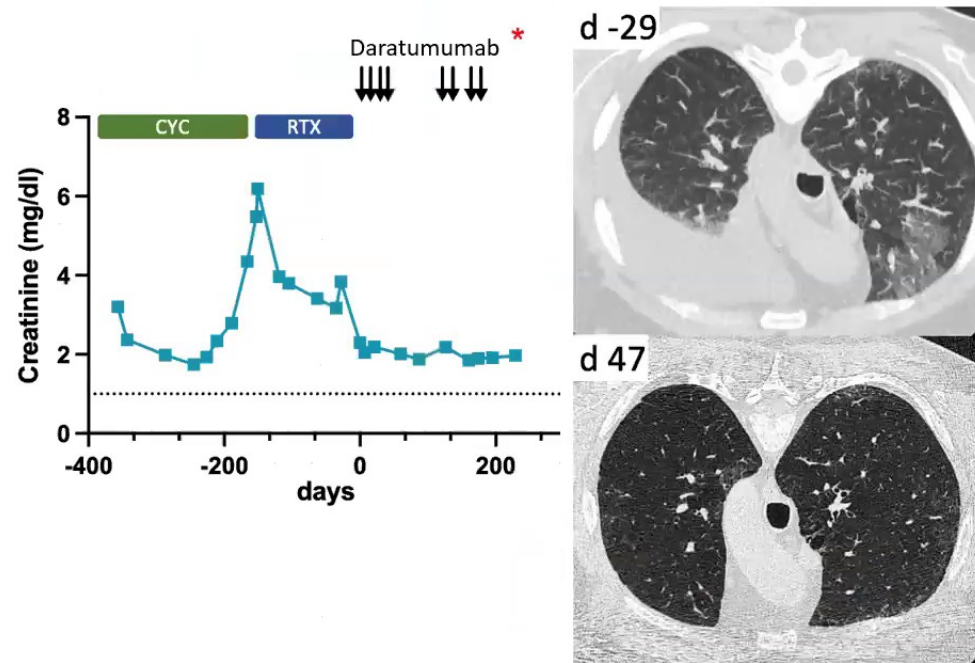


Philipp Enghard

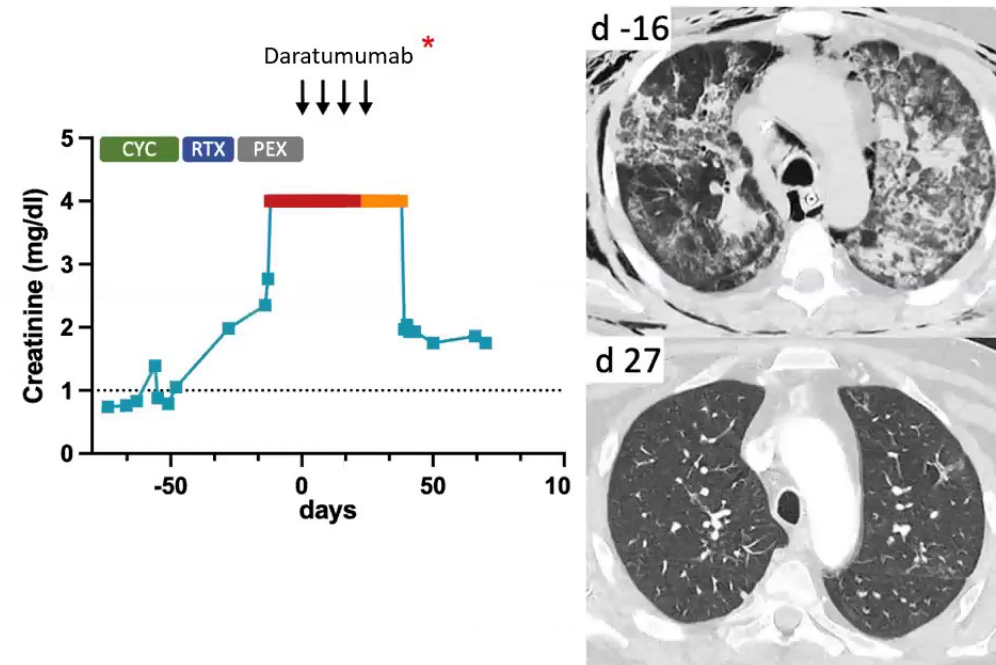


Patientennahe Forschung

Patient 1



Patient 2



* Hinweis: Daratumumab ist nicht zur Therapie von AAV zugelassen

VasCC - Vasculitis Center Charité



Ziele

- Optimierung der Patient*innenwege (ambulant, stationär, intensivmedizinisch)
- Klare Ansprechpartner*innen für Überweiser*innen
- Interdisziplinäre Patient*innenversorgung
- Integration von patientennaher klinischer Forschung

Vasculitis Center Charité



Med. Klinik m. S.
Nephrologie u. Intern.
Intensivmedizin

Med. Klinik m. S.
Rheumatologie u.
Klin. Immunologie



Experimental &
Clinical Research
Center



CeRKiD
Center for Rare
Kidney Diseases
Zentrum für seltene
Nierenerkrankungen

Vasculitis Center Charité

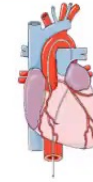


Med. Klinik m. S.
Nephrologie u. Intern.
Intensivmedizin

Med. Klinik m. S.
Rheumatologie u.
Klin. Immunologie



Experimental &
Clinical Research
Center



Klinik f. Kardiologie,
Angiologie u. Intensivmedizin

Vasculitis Center Charité



Med. Klinik m. S.
Nephrologie u. Intern.
Intensivmedizin



Med. Klinik m. S.
Rheumatologie u.
Klin. Immunologie



Experimental &
Clinical Research
Center



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Klinik f. Kardiologie,
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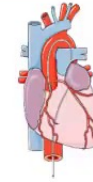


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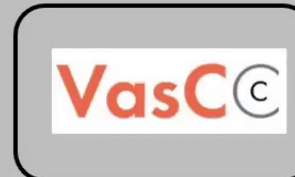


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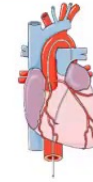
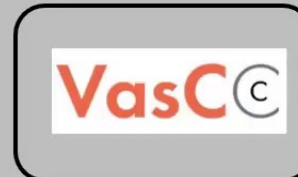
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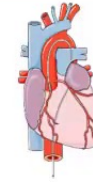
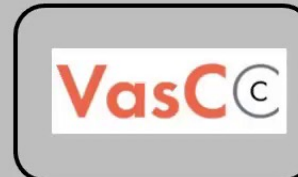
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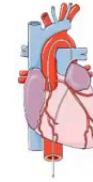
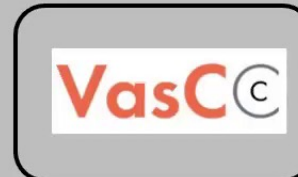


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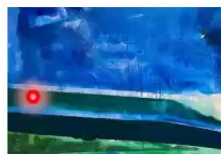
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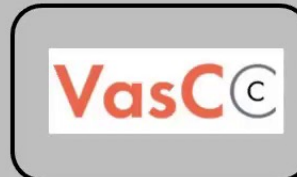


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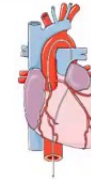
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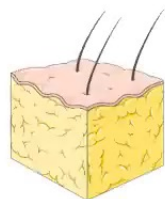


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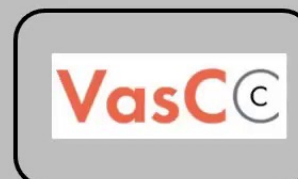
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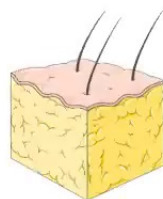


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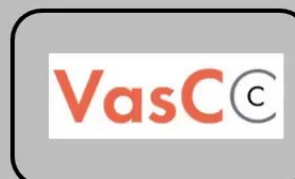
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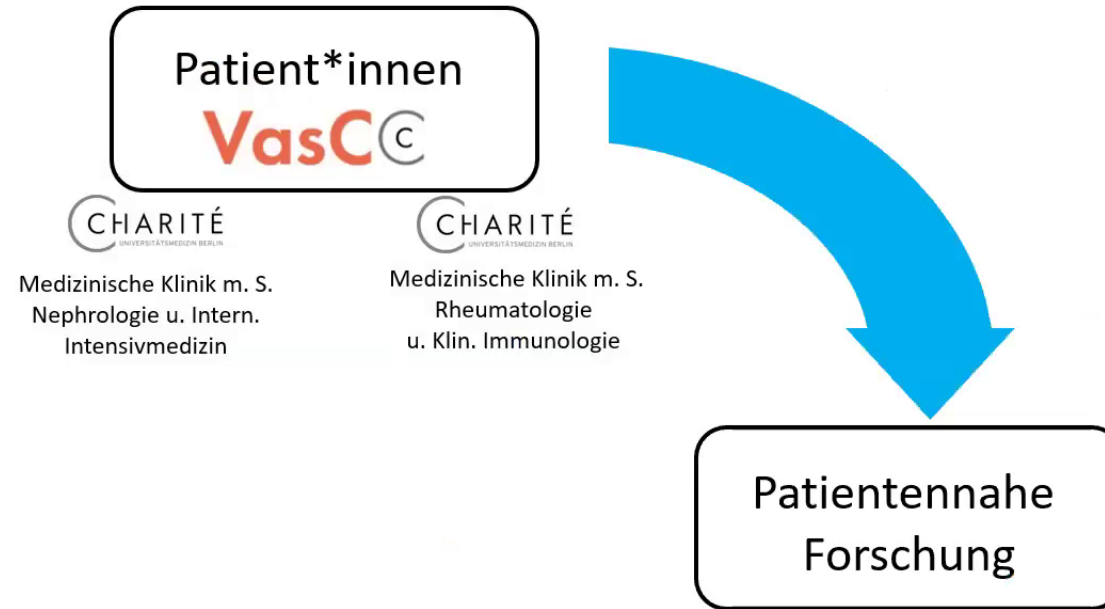


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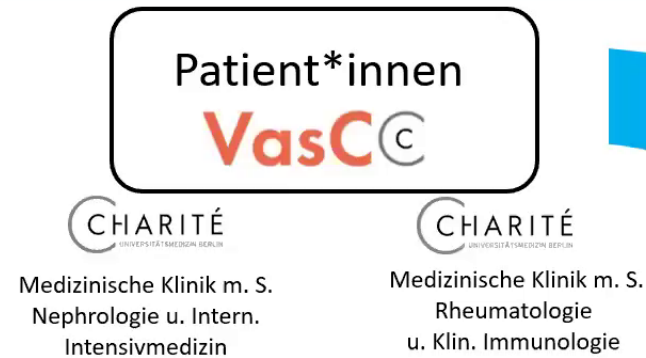


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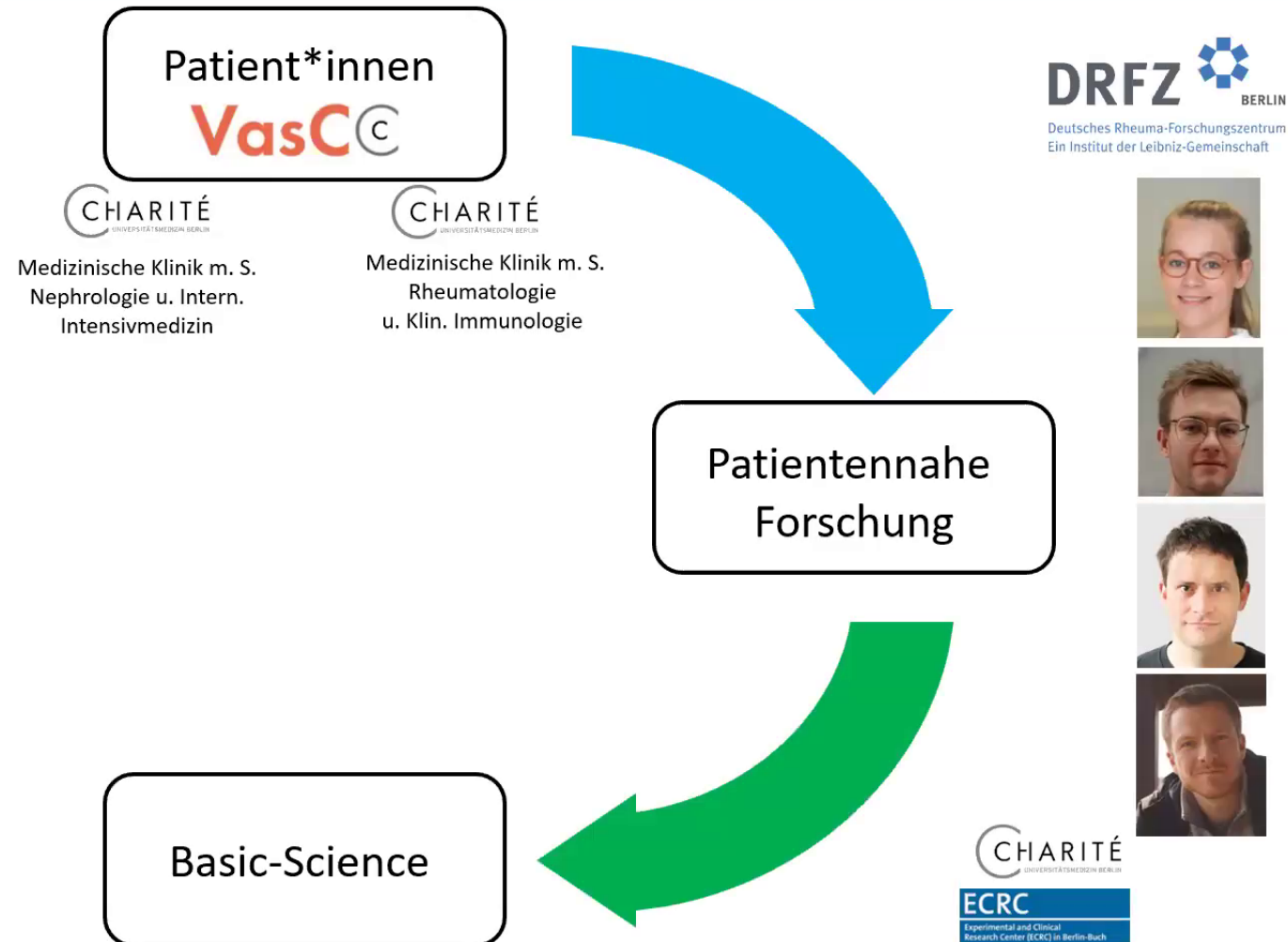
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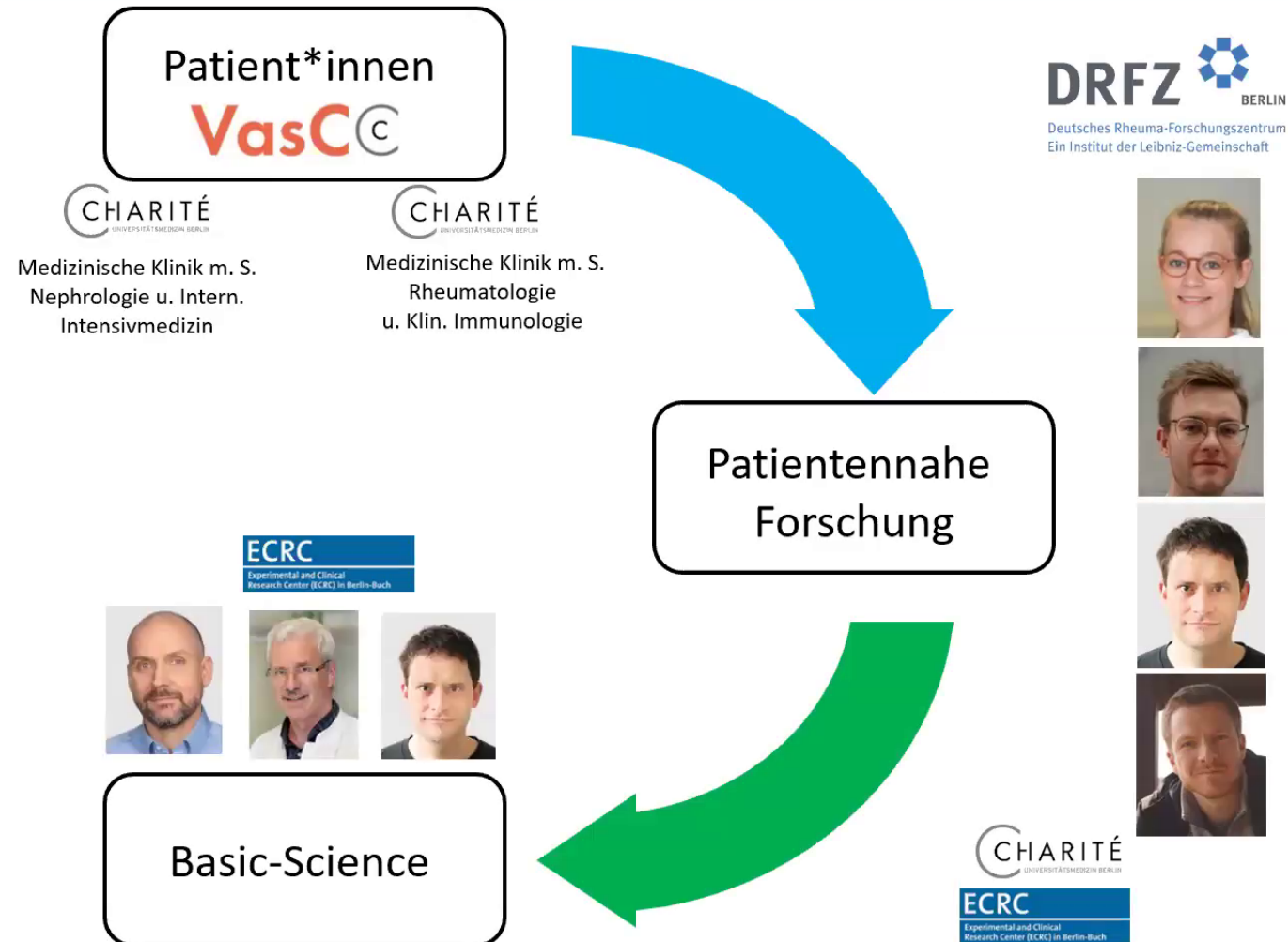


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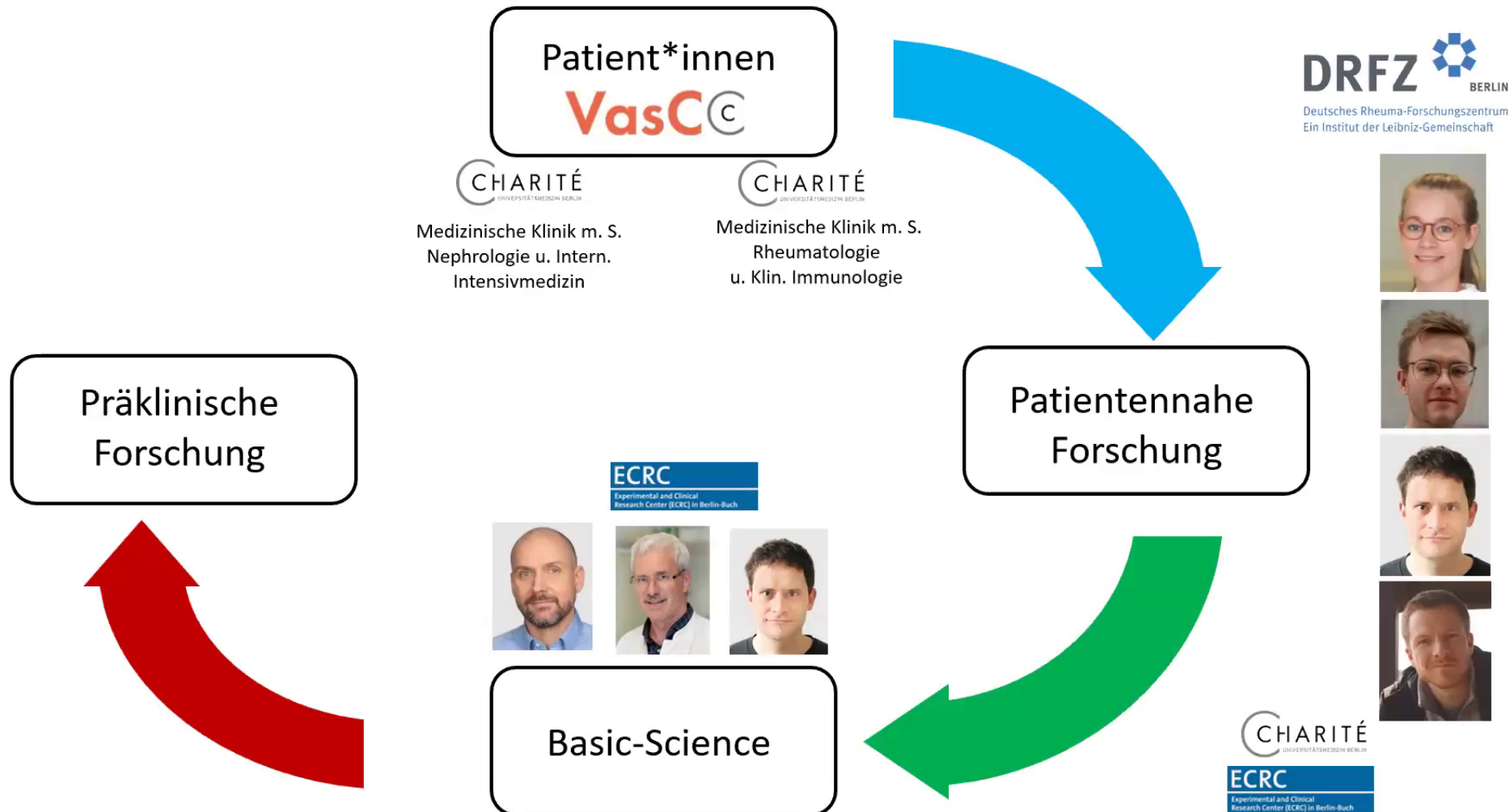
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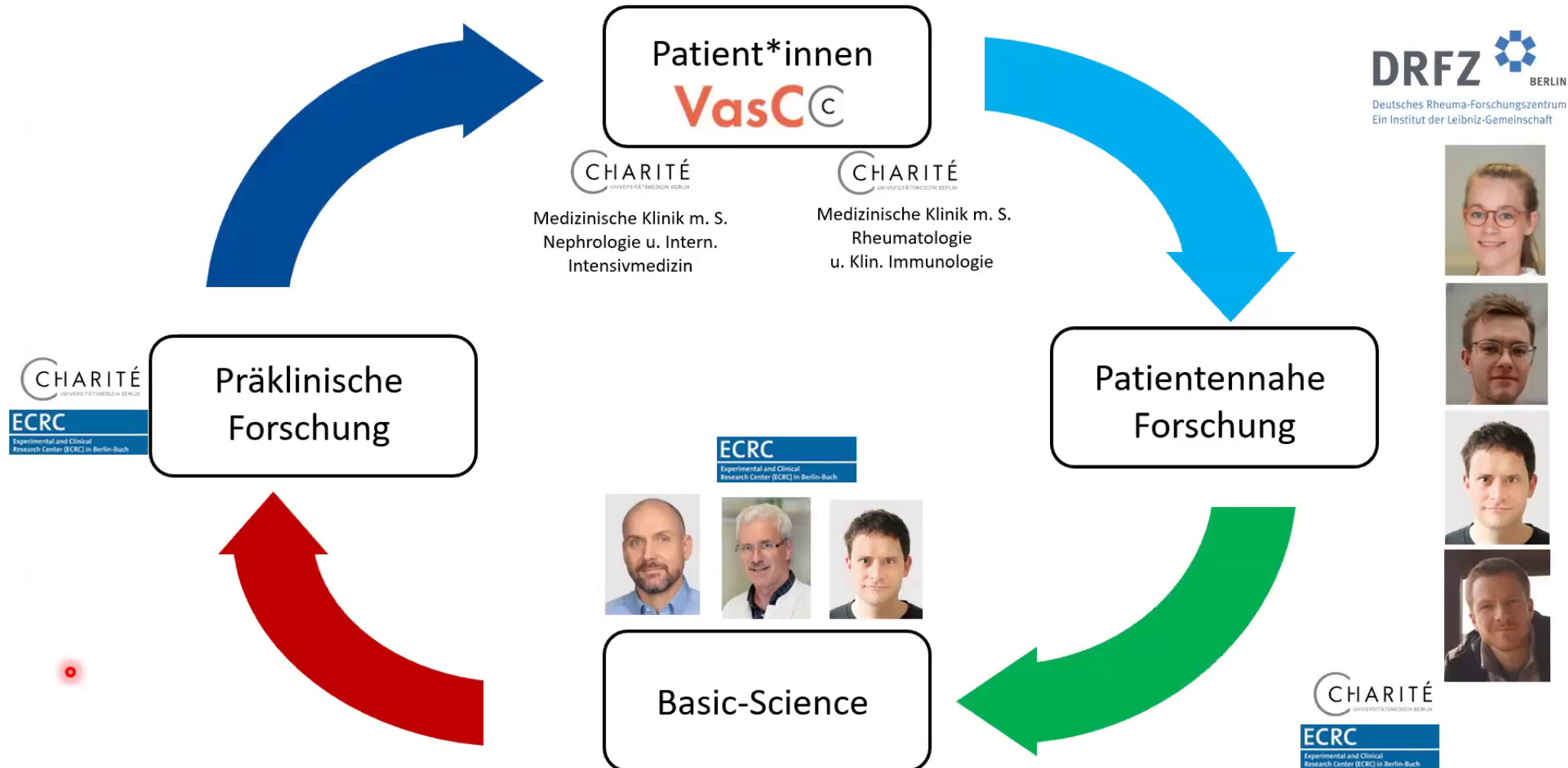
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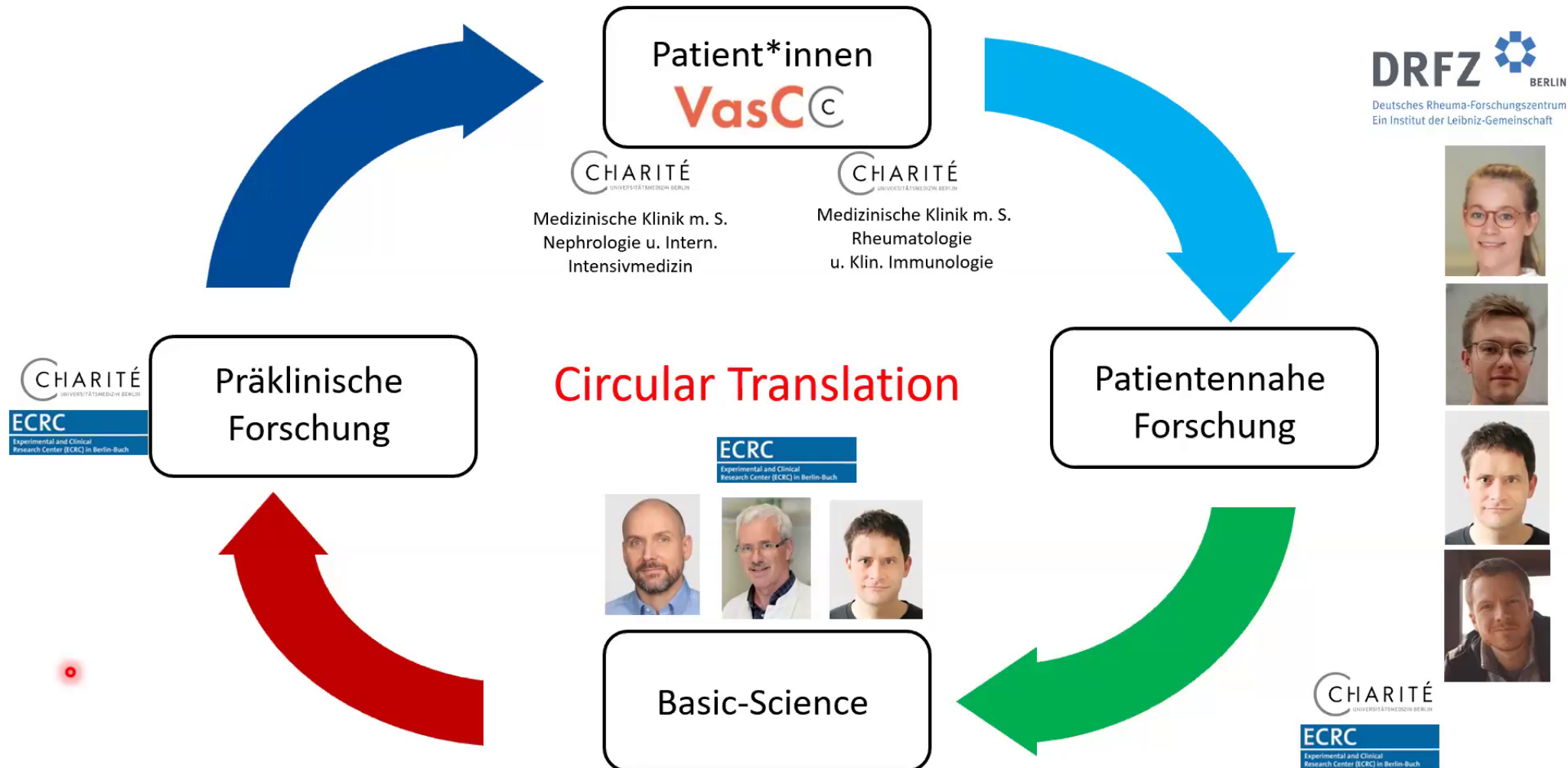
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Vielen Dank für die Aufmerksamkeit



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Die Fachpersonen können bei Vifor Pharma Switzerland AG eine vollständige Kopie des zitierten Prüfungsberichts anfordern.

Gekürzte Verschreibungsinformationen

Deutschland

▼ Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung. Dies ermöglicht eine schnelle Identifizierung neuer Sicherheitsdaten. Angehörige der Gesundheitsberufe werden gebeten, alle Verdachtsfälle von unerwünschten Wirkungen zu melden.

TAVNEOS® ▼ 10 mg Hartkapseln: **Wirkstoff:** Avacopan. **Zusammensetzung:** Jede Hartkapsel enthält 10 mg Avacopan. Sonstige Bestandteile mit bekannter Wirkung: 245 mg Macrogolglycerolhydroxystearat (Ph.Eur.). **Anwendungsgebiete:** Tavneos ist in Kombination mit einem Rituximab- oder Cyclophosphamid-Dosierungsschema indiziert zur Behandlung erwachsener Patienten mit schwerer aktiver Granulomatose mit Polyangiitis (GPA) oder mikroskopischer Polyangiitis (MPA). **Gegenanzeigen:** Überempfindlichkeit gegen den Wirkstoff oder einen der sonstigen Bestandteile. **Nebenwirkungen:** Sehr häufig: Übelkeit, Kopfschmerzen, erniedrigte Leukozytenzahl, Infektion der oberen Atemwege, Diarrhö, Erbrechen, Nasopharyngitis, erhöhte Werte in Leberfunktionstests. Häufig: Pneumonie, Rhinitis, Harnwegsinfektion, Sinusitis, Bronchitis, Gastroenteritis, Infektion der unteren Atemwege, Zellulitis, Herpes zoster, Influenza, Orale Candidose, Oraler Herpes, Otitis media, Neutropenie, Schmerzen im Oberbauch, erhöhte Kreatinphosphokinase im Blut. Gelegentlich: Angioödem. **VERSCHREIBUNGSPFLICHTIG. Fachinformation beachten. Pharmazeutischer Unternehmer:** Vifor Fresenius Medical Care Renal Pharma France, 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, Frankreich. **Stand der Information:** Februar 2022

Österreich

▼ Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung. Dies ermöglicht eine schnelle Identifizierung neuer Sicherheitsdaten. Angehörige der Gesundheitsberufe werden gebeten, alle Verdachtsfälle von unerwünschten Wirkungen zu melden.

Tavneos® Fachkurzinformation: Tavneos®10mg Hartkapsel. **Zusammensetzung:** Jede Hartkapsel enthält 10 mg Avacopan. Sonstige Bestandteile mit bekannter Wirkung: 245 mg Macrogolglycerolhydroxystearat (Ph.Eur.). **Anwendungsgebiete:** Tavneos® ist in Kombination mit einem Rituximab- oder Cyclophosphamid-Dosierungsschema indiziert zur Behandlung erwachsener Patienten mit schwerer aktiver Granulomatose mit Polyangiitis (GPA) oder mikroskopischer Polyangiitis (MPA). **Gegenanzeigen:** Überempfindlichkeit gegen den Wirkstoff oder einen der sonstigen Bestandteile. Pharmakotherapeutische Gruppe: L04AJ05 Complement Inhibitors **ATC-Code:** L04AJ05. **Inhaber der Zulassung:** Vifor France, 100-101 Terrasse Boieldieu Tour Franklin La Defense 8 92042 Paris La Defense Cedex, Frankreich. Rezept- und apothekenpflichtig. Weitere Angaben zu Warnhinweisen und Vorsichtsmaßnahmen für die Anwendung, Wechselwirkungen mit anderen Arzneimitteln oder sonstigen Wechselwirkungen, Schwangerschaft und Stillzeit und Nebenwirkungen sowie Gewöhnungseffekten sind der veröffentlichten Fachinformation zu entnehmen. Stand der Information: Letzter Stand Fachinformation

Schweiz

▼ Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung. Für weitere Informationen, siehe Fachinformation TAVNEOS® auf www.swissmedinfo.ch.

Tavneos®: Z: Avacopan. **I:** Tavneos, als ergänzende Therapie zu einer immunsuppressiven Standardbehandlung auf Basis von Rituximab oder Cyclophosphamid mit Glukokortikoiden, ist für die Behandlung erwachsener Patienten mit schwerer aktiver ANCA Vaskulitis (GPA/MPA) indiziert. **D:** Orale Einnahme morgens und abends 2x täglich 30 mg (3 Kapseln zu je 10 mg) mit Nahrung. **KI:** Überempfindlichkeit gegen den Wirkstoff oder einen der Hilfsstoffe. **VM:** Hepatotoxizität; Angioödem; Überwachung des Blutbildes (weisse Blutkörperchen); Schwere Infektionen; Reaktivierung des Hepatitis-B-Virus; Herzbeschwerden; Bösartige Tumore; Macroglycerinhydroxystearat. **S/S:** Eine Anwendung während der Schwangerschaft und bei Frauen im gebärfähigen Alter, die keine Verhütungsmethode anwenden, ist nicht empfohlen. Es ist nicht bekannt, ob Avacopan in die Muttermilch ausgeschieden wird. Der Nutzen des Stillens für das Kind sollte gegen den Nutzen der Behandlung für die Patientin abgewogen werden. **UW:** Sehr häufig: Infektion der oberen Atemwege, Nasopharyngitis; Kopfschmerzen; Erbrechen, Durchfall, Übelkeit; erhöhter Lebertest; verminderte Anzahl weisser Blutkörperchen. Häufig: Lungenentzündung, Infektion der unteren Atemwege, Influenza, Bronchitis, Zellulitis, Infektion der Harnwege, Herpes zoster, Sinusitis, orale Candidose, Herpes im Mundbereich, Otitis media, Rhinitis, Gastroenteritis; Neutropenie; Oberbauchschmerzen; Anstieg der Kreatinphosphokinase im Blut. Gelegentlich: Angioödeme. **IA:** Avacopan ist ein Substrat von CYP3A4. Die gleichzeitige Verabreichung von Induktoren oder Inhibitoren dieses Enzyms kann die Pharmakokinetik von Avacopan beeinflussen. Siehe Fachinformation. **P:** Tavneos 10 mg: 30 und 180 Hartkapseln. **Liste B.** Detaillierte Informationen: www.swissmedinfo.ch. Stand der Information: September 2022. **Zulassungsinhaber:** Vifor Fresenius Medical Care Renal Pharma Ltd., St. Gallen. **Vertrieb:** Vifor Pharma Switzerland AG, CH-1752 Villars-sur-Glâne | CH-AVA-2300011