

!" #&/  
4;O <548G=>3> 70AB>AC20==O ;V:0@AL:>3> 70A>1C

\$□ ,□  
(ENDOFALK□)

!;:04:  
4VNGV @5G>28=8: 1 ?0:5B (55,318 3 ?>@>H:C) <0:@>3>;C 3350 52,500 3, =0B@VN E;>@84C 1,400 3,  
=0B@VN 1V:0@1>=0BC 0,715 3, :0;VN E;>@84C 0,185 3;  
4>?>28=8: A0E0@8= =0B@VN, :@5<=VN 4V>:A84 :;>W4=89 1572>4=89, 0@><0B870B>@ <0@0:CW,  
0@><0B870B>@ 0?5;LA8=>289.

V:0@AL:0 D>@<0. >@>H>: 4;O >@0;L=>3> @>7G8=C.  
A=>2=V DV78:>-EVABV: 1V;0 ?>@>H:>?>4V1=0 AC28=.

\$0@<0:>B5@0?52B8G=0 3@C?0. A<>B8G=V ?@>=>A=V 70A>18. 0:@>3>;, :<1V=0FVW.  
>4 ""% 06A D65.

\$0@<0:>;>3VG=V 2;0AB82>ABV.

\$0@<0:>48=0  
=4>D0;L: T AC;V BV2 V <0:@>3>;C 4;O >45@60==O V7>B>=VG=>3> @>7G8=C 4;O >G8I5==O  
:8H5G=8:C.  
\$0@<0:>48=0;O30T 2 V=4C:C20==V 4V0@5W. 8H5G=8: 28?>@>6=NTBLAO B0 >G8ICTBLAO.  
;5:B@>;VB8, I> B>2>7G8=V, 710;0=A>20=V B0:, I>1 70157?5G8B8 ?@8?8=5==O 72>@>B=>3> ?@>F5AC  
01A>@1FVW V A5:@5FVW 2>48 B0 5;5:B@>;V BV2 C B@02=>4020==O 28A>:><>;5:C;O@=>3>  
<0:@>3>;C 70157?5GCT V7>>A<>;O@=C :>=F5=B@0FVN, 4;O O:>W E0@0:B5@=0 :>=F5=B@0FVO  
G0AB>;, ?>@V2=O=0 7 B0:>N C ?;072V. &5 70?>1V30T 1C4L-O:V9 ACBBT2V9 7A2VB<< :8H5G=8:C B0  
20A:C;O@=>N ?>@>6=8=>N. 024O:8 B0:>A<>;O@=>ABV 2?;82 =0 10;0=A 5;5:B@>;V BV2 01> @V48=8  
2>@30=V7 2V4ACB=V9.

\$0@<0:>:V=5B8:0.

0:@>3>; 3350 T V=5@B=8< 7'T4=0==O<, O:5 ?V440TBLAO ;8H5 3;8=0==N C H;C=:>2>-.8H:>2<  
0:@>3>;C 3350, < 1% 2V4 22545=>W 4>78, 282>48BLAO 7 A5G5N.

;V=VG=V E0@0:B5@8AB8:8.

>:070==O.

;O >G8I5==O :8H5G=8:C ?5@54 :;>=>A:>?VTN.

@>B8?>:070==O.

V428I5=0 GCB;82VABL 4> 4VNG8E @5G>28=, V=H8E<0:@>3>;V2 01> 4> >4=>3> 7 V=3@54VT=BV2,  
I> 2E>4OBL 4> A;:04C ;V:0@AL:>3> 70A>1C.  
8H:>20 =5?@>EV4=VABL 01> ?V4>7@0 =0 :8H:>2C =5?@>EV4=VABL, H;C=:>2>-.8H:>20  
>1AB@C:FVO, H;C=:>2>-.8H:>20 ?5@D>@0FVO, @878: H;C=:>2>-.8H:>2>W ?5@D>@0FVW, :0@F8=>  
<0 B0 V=HV BO6:V 70?0;L=V 70E2>@N20==O :8H5G=8:C (C B>289 :>;VB, E2>@>10 @>=0), B>:A8G=89  
<530:>;>=, ?>@CH5==O 28?>@>6=5==O H;C=:0.  
=4>D0;L: =5 A;V4 70AB>A>2C20B8 E2>@8<, O:V 7=0E>4OBLAO C =5A2V4<< =0?V2A2V4<< E2>@8  
<, AE8;L=8< 4> 0A?V@0FVW G8 2V4@86:8, ?@8 7030;L=V9 A;01:>ABV 01> ?>@CH5==V :>2B0;L=>3>  
@5D;5:AC.

70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9.

V:8, O:V 70AB>A>2CNBL ?5@>@0;L=> 2?@>4>26 45;V;L:>E 3>48= 4> 01> ?V4 G0A ?@89>D0;L:C,  
<>6CBL 1CB8 282545=V 7V H;C=:>2>-.8H:>2>3> B@0:BC 01> 6 WE ?>3;8=0==O <>65 1CB8 7=865=5 01>  
?>2=VABN ?@8?8=5=5. &5 AB>ACTBLAO, 7>:@5<0, ;V:0@AL:8E 70A>1V2 V7 2V4AB@>G5=8<  
282V;L=5==O 70 68BBT28<8 ?>:070==O<8 FV ;V:8 T 01A>;NB=> =5>1EV4=8<8, A;V4 C=8:0B8 WE  
?5@>@0;L=>3> ?@89>A>2C20B8 F59 (FV) ;V:0@AL:V9 (:V) 70AV1 (70A>18) 2 V=HV9 ;V:0@AL:V9  
D>@ 7=09B8 0;LB5@=0B82C.  
>6;820 270T<>4VO ELISA) ?@8 4V03=>AB8G=>A;V465==V :8H:>2>W @V48=8, I> 1C;0 282545=0.

>B>289 @>7G8= =5 <>6=0 7

**A>1;82>ABV 70AB>AC20==O.**

=4>D0;L: A;V4 70AB>A>2C20B8 ;8H5 ?V4 <548G=8< =03;O4<< E2>@8< ;VB=L>3> 2V:C, ?0FVT=B0< 7  
@5D;N:A-57>D03VB<< 01> =0O2=>N A5@F52>N 0@8B7@N20=8< 01> ?V4B25@465=8<  
A8=>0B@V0;L=8< 1;>:> 01> A8=4@><< A;01:>ABV A8=CA>2>3> 2C7;0.  
0FVT=B0< 7 E@>=VG=8<8 70?0;L=8<8 70E2>@N20==O<8 :8H5G=8:C (>:@V3> ?5@51V3C V  
B>:A8G=>3> <530:>=>C) ?@5?0@0B A;V4 70AB>A>2C20B8 7 >15@56=VABN, ?V4 =03;O4<< ;V:0@O.  
=4>D0;L: =5 A;V4 70AB>A>2C20B8 E2>@8< V7 A5@F52>N =54>AB0B=VABN (NYHA V V  
ABC?5=O), =8@:>2>N =54>AB0B=VABN, 70E2>@N20==O<8 ?5GV=:8 01> 6 E2>@8< 7 28@065=>N  
453V4@0B0FVTN, >A;V;L:8 157?5:0 70AB>AC20==O ?@5?0@0BC B0:8< E2>@8< =5 1C;0 4>AB0B=L>  
4>A;V465=0. @5?0@0B =5>1EV4=> 26820B8 >15@56=> ?0FVT=B0< 7 @878:<< ?>@CH5=L 2>4=>-  
5;5:B@>;VB=>3> 10;0=AC (=0?@8::04, ?0FVT=B0< 7 ?>@CH5==O< DC=:FVW ?5GV=:8, =8@>:, ?@8  
>4=>G0A=>3V==8E 70A>1V2). C;8 70DV:A>20=V ?>>48=>:V 28?04:8 ?>@CH5=L 2>4=>-  
5;5:B@>;VB=>3> 10;0=AC C ?0FVT=V2 3@C?8 @878:C. # ?0FVT=V2 V7 A5@F52>N 01> =8@:>2>N  
=54>AB0B=VABN <>65 @>728=CB8AL 3>AB@89 =01@O: ;535=L C 7207:C 7 =04  
5 <>6=0 4>4020B8 =VO:8E V=H8E @>7G8=V2 01> 4>102>: (7>:@5<0 FC:@C 01> 0@<<0B870B>@V2,  
=5AC7G8=>< =4>D0;L:C) 4> 3>B>2>3> 4> ?5@>@0;L=>3> ?@89>7G8=C =4>D0;L:C, B> F5 <>65 7A  
<>;O@=VABL V 5;5:B@>;VB=89 A;:04 01> 6 A?@8G8=8B8 CB2>@5==O AC  
5>1EV4=> ?@>2>48B8 <>=VB>@8=3 2>4=>-5;5:B@>;VB=>3> 10;0=AC C ?0FVT=V2 3@C?8 @878:C,  
2;:NG0NG8 ?0FVT=V2 ;VB=L>3> 2V:C B0 >A;01;5=8E.

**0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.**

03VB=VABL

>A2V4C 70AB>AC20==O ?@5?0@0BC C ?5@V>4 203VB=>ABV =5<0T.

5@V>4 3>4C20==O 3@C44N

0=8E I>4> ?@>=8=:5==O <0:@>3>;C 3350 C 3@C4=5 <>;>: =5<0T.

0:@>3>; 3350 A;01:> ?>3;8=0TBLAO. =4>D0;L: <>6=0 70AB>A>2C20B8 C ?5@V>4 3>4C20==O 3@C44N,  
O:I> :>@8ABL 2V4 70AB>AC20==O 4;O <0B5@V ?5@528ICT ?>B5=FV9=89 @878: 4;O 48B8=8.

**40B=VABL 2?;820B8 =0 H284:VABL @50:FVW ?@8 :5@C20==V 02B>B@0=A?>@B< 01> V=H8<8  
<5E0=V7<0<8.**

=4>D0;L: =5 2?;820T =0 740B=VABL :5@C20B8 02B<>1V;5< 01> @>1>BC 7 <5E0=V7<0<8.

**!>AV1 70AB>AC20==O B0 4>78.**

;O ?>2=>3> >G8I5==O :8H5G=8:C =5>1EV4=> 28?8B8 4> 3, <0:A84 ;VB@V2 @>7G8=C =4>D0;L:C. 48=  
?0:5B 2V4?>2V40T 1/2;VB@0 @>7G8=C.

>7G8= 28?820B8 ?>@FVO<8 ?> 200-300 <; :>6=V 10 E28;8=, ?>:8 @5:B0;L=V ?@<<82=V 2>48 =5  
AB0=CBL ?@>7>@8<8.

0728G09 ?@89<< ?@5?0@0BC =5>1EV4=> 7025@H8B8 70 4 3>48=8 ?5@54 ?>G0B:<< 4>A;V465==O.

030;L=C =5>1EV4=C :V;L:VABL @>7G8=C B0:>6<>6=0 ?@89=OB8 C25G5@V, =0?5@54>4=V  
4>A;V465==O, 01> 6 G0AB:>2> C25G5@V =0?5@54>4=V, 0 70;8H>: =0ABC?=>3> @0=:C, 2 45=L  
4>A;V465==O.

0FVT=B8 =5 ?>28==V 26820B8 1C4L-O:C B25@4C W6C 70 2-3 3>48=8 ?5@54 ?@89<<< =4>D0;L:C V  
4> 7025@H5==O 4>A;V465==O.

@83>BC20==O @>7G8=C

>7G8= 3>BC20B8 ?5@54 26820==O<, @>7G8=ONG8 2;>48;L=8.; >A;V;L:8 1060=> 70AB>A>2C20B8 9>3>  
>E>;>465=8

**VB8.**

=4>D0;L: =5 A;V4 70AB>A>2C20B8 4VBO<, >A;V;L:8 157?5:0 70AB>AC20==O ?@5?0@0BC 2 FV9  
2V:>2V9 3@C?V ?0FVT=V2 =5 1C;0 =0;56=8< G8=>< 282G5=0.

**5@54>7C20==O.**

@8 ?5@54>7C20==V <>6;820 BO6:0 4V0@5O. # @07V 7=0G=>3> ?5@54>7C20==O <>6CBL  
 >GV:C20B8AO ?>@CH5==O @V48==>3>, 5;5:B@>;VB=>3> V :8A;>B=>-;C6=>3> 10;0=AC. 5>1EV4=>  
 ?@>2>48B8 045:20B=5 70  
 /:I> 28=8:0T @V48==89, 5;5:B@>;VB=89 01> :8A;>B=>-;C6=89 48A10;0=A, =5>1EV4=> B0:>6  
 2V4=>2;N20B8 5;5:B@>;VB8 B0 268B8 70E>4V2 4;O 2V4=>2;5==O :8A;>B=>-;C6=>3> 10;0=AC.  
 @8 0A?V@0FVW <>65 @>728=CB8AO B>:A8G=89 ;535=5289 =01@O:, O:89 ?>B@51CT =5309=8E  
 V=B5=A82=8E ;V:C20;L=8E 70E>4V2, 2;;NG0NG8 25=B8;OFVN ;535=L ?V4 ?V428I5=8< B8A:>

>1VG=V @50:FVW.

!8AB5<0 >@30=V2	'0AB>B0 2V4?>2V4=> 4> >=25=FVW MedDRA	
	G0AB> (□ 1/100 4> □ 1/10)	4C65 G0AB> (□ 1/10)
(;C=>2>-:8H:>2V @>7;048	;N20==O, 014>	C4>B0, 2V4GCBBO ?5@5?>2=5==O B0 74CBBO 682>B0.

&V A8<8 A?>AB5@V30NBLAO 7451V;LH>3> 2=0A;V4>: 26820==O 2V4=>A=> 25;8:>W :V;L:>ABV  
 @V48=8 ?@>BO3<< :>@>B:>3> ?@> =002=V H;C=>2>-:8H:>2V A8<8, G0AB>BC ?@89>D0;L:C  
 =5>1EV4=> B82> 7<5=H8B8 01> ?@8?8=8B8 ?@89<< ?@5?0@0BC 4> CAC=5==O A8

!8AB5<0 >@30=V2	'0AB>B0 2V4?>2V4=> 4> >=25=FVW MedDRA	
	V4:> (□ 1/1000 4> □ 1/100)	4C65 @V4:> (□ 1/10000)
030;L=V ?>@CH5==O	030;L=5 =574C60==O B0 157A>==O.	
!5@F52V ?>@CH5==O		!5@F520 0@8B
01>@0B>@=V ?>:07=8:8		# 450:8E ?0FVT=BV2 <>65 A?>AB5@V30B8AO 7=865==O @V2=O :0;LFDVN, :0;VN, =0B@VN C A8@>20BFV :@>2V.
>@CH5==O 7 1>:C F5=B@0;L=>W =5@2>2>W A8AB5<8		52@>;>3VG=V ?>@CH5==O O: =0A;V4>: :>;820==O 5;5:B@>;VB=>3> 10;0=AC <>6CBL ?@8725AB8 4> ;53:>W 457>@VT=B0FVW 01> 4> C7030;L=5=8E =0?04V2.
>@CH5==O VW A8AB5<8		@>?82O=:0, @8=>@5O, 2V4GCBBO A25@156C 01> 45@<0B8B (V <>2V@=>, 0;5@3VG=>3> ?>E>465==O), 28A8?0==O, A8=4@<< 2V=:5, 0=0DV;0:B8G=89 H>:.

#2030!  
 # ;VB5@0BC@V =02>4OBLAO 40=V ?@> 420 28?04:8 A8=4@>@V-59A0, I> A?>AB5@V302AO O:  
 @57C;LB0B 1;N20==O ?VA;O 26820==O ?@><820;L=8E @>7G8=V2, O:V

"5@ABV. 5 @>:V2. 5 70AB>A>2C20B8 ?VA;O 70:V=G5==O B5@ABV, 707=0G5=>3> =0 C?0:>2FV.

#<>28 715@V30==O. 5 ?>B@51CT A?5FV0;L=8E C<>2 715@V30==O. 15@V30B8 2 =54>ABC?=>.  
>B>289 @>7G8= ?@840B=89 4;O 28:>@8AB0==O 2?@>4>26 3 3>48=, O:I> 2V= 715@V30TBLAO ?@8 B5  
25 >! 01> 2?@>4>26 48 3>48=, O:I> 2V= 715@V30TBLAO ?@8 B5 2 >! 8 >! (2 E>;>48;L=8:C).

#?0:>2:0. > 55, 318 3 ?>@>H:C C ?0:5BV; ?> 6 ?0:5BV2 C :>@>1FV 7 :0@B>=C.

**0B53>@VO 2V4?CA:C. 57 @5F5?B0.**

**8@>1=8:.**

@. \$0;L: \$0@<0 <1%, V<5GG8=0/Dr. Falk Pharma GmbH, Germany.

**VAF57=0E>465==O 28@>1=8:0 B0 9>3> 04@5A020465==O 4VO;L=>ABV.**

O9=5=2515@HB@0AA5 5, -79108 \$@091C@3, V<5GG8=0 / Leinenweberstrasse 5, D-79108 Freiburg,  
Germany.

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