

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

!□ \$□ ,□
(SALOFALK®)

!,:04:

4VNG0 @5G>28=0: <5A0;078=;
1 AC?>78B>@V9 250 <3 <5A0;078=C (5-0A0;VF8;>2>W :8A;>B8);
4>?>28=0: 68@ B25@489.
1 AC?>78B>@V9 A0;VF8;>2>W :8A;>B8);
4>?>28=8: 68@ B25@489, A?8@B F5B8;>289, =0B@VN 4>:C70B.

V:0@AL:0 D>@<0. !C?>78B>@VW @5:B0;L=V.
A=>2=V DV78:>-EVABV: AC?>78B>@VW 2V4 1V;>3> 4> :@5<2>3> :>;L>@C, B>@?54>?>4V1=>W
D>@<8, 7 >4=>@V4=>N :>=A8AB5=FVTN B0 =5?>H:>465=>N, 3;045=L:>N ?>25@E=5N.

\$0@<0:>B5@0?52B8G=0 3@C?0. @>B870?0;L=V 70A>18, I> 70AB>A>2CNBLAO 4;O ;V:C20==O
70E2>@N20=L :8H5G=8:C. >4 ""% 07!02.

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

\$0@<0:>48=0
5E0=V7< ?@>B870?0;L=>W 4VW =52V4><89. 57C;LB0B8 4>A;V465=L in vitro A2V4G0BL, I> ?52=C
@>;L <65 <0B8 V=3V1C20==O ;V?>:A835=078.
C;> B0:>6 ?@>45<=>AB@>20=> 2?;82 =0 :>=F5=B@0FVN ?@>AB03;0=48=V2 C A;87>2V9 >1>;>=FV
:8H5G=8:C. 5A0;078= (5-0A0;VF8;>20 :8A;>B0/5-!) <65 B0:>6 4VOB8 O: ?>3;8=0G @048:0;V2
@50:B82=8E A?>;C: :8A=N.
5A0;078= ?@8 @5:B0;L=>
>;V=VG=V 40=V, I> 107CNBLAO =0 B@048FV9=8E 4>A;V465==OE I>4> 157?5:8, D0@<0:>;>3VW,
35=>B>:A8G=>ABV, :0=F5@>35==>ABV (=0 IC@0E) 01> B>:A8G=>ABV 4;O @5?@>4C:B82=>W A8AB5
<8, =5 2:07CNBL ?@> >A>1;82C =5157?5:C 4;O ;N48=8.
C;> 2V4 =8@:>2C B>:A8G=VABL (=8@:>289 ?0?V;O@=89 =5:@>7 B0 ?>H:>465==O 5?VB5;VN 2 ?@>:A8
<0;L=8E :0=0;LFOE (Pars convoluta) 01> FV;>3> =5D@>=0) 2 4>A;V465==OE B>:A8G=>ABV ?@8
70AB>AC20==V ?>2B>@=8E 28A>:8E ?5@>@0;L=8E 4>7 <5A0;078=C. ;V=VG=0 206;82VABL F8E 40=8E
=52V4><0.

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

030;L=V 2;0AB82>ABV <5A0;078=C

>3;8=0==O

>3;8=0==O <5A0;078=C T =0928I8< C ?@>:A8<0;L=V9 G0AB8=V :8H5G=8:C V =09=86G8< C

48AB0;L=V9 9>3> G0AB8=V.

V>B@0=AD>@<0FVO

5A0;078= <5B01>;V7CTBLAO O: 4>A8AB5<=> C A;87>2V9 >1>;>=FV :8H5G=8:C, B0: V 2 ?5GV=FV C
D0@<0:>;>3VG=> =50:B82=C N-0F5B8;-5-0A0;VF8;>2C :8A;>BC (N-AF-5-!). G5284=>, I> 0F5B8;N20==O
=5 70;568BL 2V4 D5=>B8?C 0?0@0BC 4;O 0F5B8;N20==O E2>@>3>. 5O:5 0F5B8;N20==O B0:>6
2V41C20TBLAO 7024O:8 4VW 10:B5@V9 C B>2AB>N-AF-5-!7 1V;;<8 AB0=>28BL 2V4?>2V4=> 43 % V
78 %.

82545==O/5:A:@5FVO

5A0;078= V 9>3> <5B01>;VB N-AF-5-!282>4OBLAO 7 D5:0;VO<8 (>A=>2=0 G0AB8=0), =8@:0<8
(20@VNT 70;56=> 2V4 B8?C 70AB>AC20==O, D0@<0F52B8G=>W D>@<8 V H;OEC 282V;L=5==O
<5A0;078=C 2V4?>2V4=>) V 7 6>2GN (=57=0G=0 G0AB8=0). 8@:>20 5:A:@5FVO 2V41C20TBLAO
?5@5206=> C 283;O4V N-AF-5-!. ;87L:> 1 % 2V4 7030;L=>W 22545=>W >@0;L=> 4>78 <5A0;078=C
5:A:@5BCTBLAO C 3@C4=5 <>;>;>, 3>;>2=8< G8=>< C 283;O4V N-AF-5-□!□.

A>1;82>ABV AC?>78B>@VW2 !0;>D0;L:C 500 <3

>7?>4V;

!F8=BV3@0DVG=5 4>A;V465==O 7 >7?>2AN465==O >1<565=5 ?5@H 70 2A5 ?@O<>N :8H:>N V
@5:B>A83<>?>4V1=8< 2V44V;>78B>@VW !0;>D0;L:C >A>1;82> ?@840B=V 4;O ;V:C20==O ?@>:B8BC
(28@07:>2>3> :>;VBC ?@O<>W :8H:8).

>3;8=0==O

V: :=F5=B@0FVW 2 ?;074=>@07>2>3> 70AB>AC20==O, 0 B0:>6 ?@8 B5@0?VW 2?@>4>26 45:V;L:>E
B86=V2 500 <3 <5A0;078=C 3 @078 =0 45=L C 283;O4V AC?>78B>@VW2 !0;>D0;L:C 20@VN202 2V4 0,1
4> 1,0 N-AF-5-!2V4 0,3 4> 1,6 # 45O:8E 28?04:0E ?V: :=F5=B@0FVW 5-!2 ?;074>AO302AO C <560E 1
3>48=8 ?VA;O 70AB>AC20==O.

82545==O

VA;O >4=>@07>2>3> 70AB>AC20==O 500<3 <5A0;078=C C 283;O4V AC?>78B>@VO !0;>D0;L:C
?@81;87=> 11 % (2?@>4>26 72 3>48=) V ?VA;O :V;L:0B86=52>W B5@0?VW 500<3 <5A0;078=C 3 @078
=0 45=L C 283;O4V AC?>78B>@VW2 !0;>D0;L:C ?@81;87=> 13 % 2V4 C2545=>W 4>78 5-!282>48;8AL
V7 A5G5N. @81;87=> 10 % 2V4 C2545=>W 4>78 282>48;>AL V7 6>2GN.

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

>:070==O.

V:C20==O 703>AB@5=L B0 ?@>DV;0:B8:0 @5F8482V2 28@07:>2>3> :>;VBC, >k565=>3> ?@O<>N
:8H:>N.

@>B8?>:070==O.

V?5@GCB;82VABL 4><5A0;078=C, 4> 1C4L-O:>3> 7 :=5=BV2 ?@5?0@0BC 01> 4> A0;VF8;0BV2,
28@07:>20 E2>@>10 H;C=:0 B0 420=04FOB8?0;>W :8H:8 2 AB04VW 703>AB@5==O, BO6:0 ?5GV=:>20
B0/01> =8@:>20 =54>AB0B=VABL, 35<>@03VG=89 4V0B57.

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

!75FV0;L=8E 4>A;V465=L ;V:0@AL:>W 270T<>4VW =5 ?@>2>48;>AL.

V4 G0A :>3> ;V:C20==O ?@5?0@0B< !0;>D0;L: B0 070BV?>@8=><, 6-<5@:0?B>?C@8=>< 01>
BV>3C0=V=>< C 45O:8E 4>A;V465==OE 1C;> 28O2;5=> 1V;LHC G0AB>BC AC?@5A82=8E 5D5:BV2, I>
=V18B> A2V4G8BL ?@> =0O2=VABL 270T<>4VW, >4=0: <5E0=V7< 270T<>4VW 2AB0=>2;5=89 =5
?>2=VABN. 5:>5=4CTBLAO @53C;O@=> :=B@>;N20B8 @V25=L ;59:>F8BV2, 0 @568< 4>7C20==O
BV>?C@8=V2 A;V4 2V4:>@83C20B8.

40=V ?@> B5, I> <5A0;078= <>65 7=878B8 0=B8:>03C;OFV9=C 4VN 20@D0@8=C.

>6;825 ?>A8;5==O 3V?>3;V:5W 4VW ?>EV4=8E AC;LD>=V;A5G>28=8, B>:A8G=>W 4VW
<5B>B@5:A0BC. :B82=VABL DC@>A5=>;0:B>=C, AC;LD0=V;015=5F84C B0 AC;LDV=?V@07>=C) <>65
A;01H0B8. 5A0;078= <>65 ?>B5=FN20B8 =51060=C 4VN 3;N:>:>@B8:>W4V2 =0 A;87>2C >1>;>=:C
H;C=:0, 7<5=HC20B8 2A<>:BC20==O 483>:A8=C.

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

V4 G0A B0 ?VA;O ;V:C20==O =5>1EV4=> ?@>2>48B8 0=0;V78 :@>2V (@>73>@=CB89 0=0;V7 :@>2V;
?0@0<5B@8 DC=:FVW ?5GV=:8, B0:V O: " 01> !"; :@50B8=V= A8@>20B:8) B0 A5GV (B5AB>2V AA04).
@VT=B>2=> 0=0;V78 @5:><5=4CTBLAO @>18B8 G5@57 14 4=V2 2V4 ?>G0B:C ;V:C20==O V ?>BV< 15
2-3 @078 7 V=B5@20;0<8 4 B86=V.

/:I> @57C;LB0B8 4>A;V465=L =>@<0;L=V, @CB8==V ?5@52V@:8<>6CBL ?@>2>48B8AL 4 @078 =0
@V.; 0;5 ?@8 ?>O2V V=H8E 4>40B:>28E A8IEV4=> 7@>18B8 B5@2>.

>15@56=VABN A;V4 70AB>A>2C20B8 E2>@8< 7 ?>@CH5==O< DC=:FVW ?5GV=:8.

>B@V1=> 7 >15@56=VABN 70AB>A>2C20B8 AC?>78B>@VW !0;>D0;L:C E2>@8< 7 ?>@CH5==O<8
DC=:FV9 =8@>.. 5>1EV4=> @53C;O@=> :=B@>;N20B8 DC=:FVN =8@>.. 0 A0<5 28BC A5G>28=8
:@>2V, :@50B8=V=C C ?0FVT=BV2 7 ?@>B5W=C@VTN. @8 ?>3V@H5==V DC=:FVW =8@>:

2?@>4>26 ;V:C20==O A;V4<0B8 =0 C207V V=4C:>20=C <5A0;078=>< B>:A8G=VABL 2V4=>A=> =8@>..
%2>@V 7 ;535=528<8 70E2>@N20==O<8, 7>:@5<0 7 0AB<>N, ?>28==V 7=0E>48B8AL ?V4 =03;O4<<
;V:0@O ?@>BO3< :C@AC ;V:C20==O AC?>78B>@VO<8 !0;>D0;L:C.

%2>@V, O:V<0NBL @50:FVW 3V?5@GCB;82>ABV, 2;:NG0NG8 AC4<8, 3>AB@89 1V;L C 682>BV,
30@OG:C, A8;L=89 3>;>2=89 1V;L B0 28A8?0==O, =0 ?@5?0@0B8, I>A8<>ABV B5@0?VN A;V4
=5309=> ?@8?8=8B8.

5<0T ?>B@518 7<5=HC20B8 4>78 ?0FVT=B0< ;VB=L>3> 2V:C.

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

0=8E ?@> 70AB>AC20==O AC?>78B>@VW2 !0;>D0;L:C C 203VB=8E 6V=>: =54>AB0B=L>, ?@>B5
40=V ?@> 70AB>AC20==O C >1<565=>W :V;L:>ABV 203VB=8E 2:07CNBL =0 2V4ACB=VABL
=51060=8E 2?:82V2 <5A0;078=C =0 ?5@51V3 203VB=>ABV 01> =0 74>@>2O ?;>40 B0 (01>)
=>2>=0@>465=>3>. 0 AL>3>4=V =VO:V V=HV 5?V45;>3VG=V 40=V, I><0NBL 2V4=>H5==O 4>
?@5?0@0BC, =54>ABC?=V. >4=>3> 70AB>AC20==O 2?@>4>26 203VB=>ABV <5A0;078=C C 28A>:V9
4>7V (2-4 3 ?5@>@0;L=>) ?>2V4><;O;>AL ?@> =8@:>2C =54>AB0B=VABL C =>2>=0@>465=>3>. C;8
?>2V4><;5==O ?@> ?>@CH5==O 7 1>:C A8AB5<8 :@>2V (:59:>?5=VO, B@><1>F8B>?5=VO, 0=5
2>=0@>465=8E, <0B5@V O:8E 70AB>A>2C20;8 <5A0;078=
>A;V465==O =0 B20@8=0E ?@8 ?5@>@0;L=>
!C?>78B>@VW !0;>D0;L:C =5>1EV4=> ?@89<0B8 ?@>BO3>< 203VB=>ABV ;8H5 B>4V, :>;8 >GV:C20=0
:>@8ABL 2V4 70AB>AC20==O ?5@52060T <>6;8289 @878:.
N-0F5B8;-5-0A0;VF8;>20 :8A;>B0 V,<5=H>N N, <5A0;078= 5:A:@5BCNBLAO C 3@C4=5 <>;>: 0
AL>3>4=V T ;8H5 >1<565=89 4>A2V4 70AB>AC20==O C 6V=>: C ?5@V>4 3>4C20==O 3@C44N. 5
<>6=0 28;;NG8B8 @50:FV9 3V?5@GCB;82>ABV C 3@C4=>W 48B8=8, B0:8E O: 4V0@5O. B65
AC?>78B>@VW !0;>D0;L:C <0NBL 70AB>A>2C20B8AL C ?5@V>4 3>4C20==O 3@C44N ;8H5 B>4V,
:>;8 >GV:C20=0 :>@8ABL 4;O <0B5@V ?5@52060B8<5 <>6;8289 @878: 4;O 48B8=8. /:I> C 3@C4=>W
48B8=8 @>728=5BLAO 4V0@5O, 3>4C20==O 3@C44N A;V4 ?@8?8=8B8.

**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.**

VO:>3> 2?;82C =0 740B=VABL :5@C20B8 02B<>1V;5< B0 ?@0FN20B8 7 <5E0=V7<0<8 =5
A?>AB5@V30;>AL. # 28?04:0E, O:I> ?V4 G0A ;V:C20==O ?@5?0@0B< A?>AB5@V30TBLAO 70?0
<>@>G5==O, A;V4 CB@8<0B8AO 2V4 :5@C20==O B@0=A?>@B=8<8 70A>10<8 B0 @>1>B8 7 <5E0=V7
<0<8.

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

!0;>D0;L:, AC?>78B>@VW ?> 250 <3, 500 <3

&59 ;V:0@AL:89 70AV1 ?@87=0G5=89 4;O @5:B0;L=>3> 22545==O.

>@>A;V

V:C20==O 703>AB@5=L 28@07:>2>3> :>;VBC:

70;56=> 2V4 V=482V4C0;L=>W ;V=VG=>W ?>B@518 2 AC?>78B>@VW !0;>D0;L:C 250 <3 01>
1 AC?>78B>@V9 !0;>D0;L:C 500 <3 22>4OBL 4> ?@O<>W :8H:8 3 @078 =0 4>1C (5:2V20;5=B=> 1500 <3
<5A0;078=C =0 4>1C).

@>DV;0:B8:0 @5F8482V2 28@07:>2>3> :>;VBC:

1 AC?>78B>@V9 !0;>D0;L:C 250 <3 3 @078 =0 4>1C (5:2V20;5=B=> 750 <3 <5A0;078=C =0 4>1C).

VB8. 5<0T 4>AB0B=VE 40=8E ?@> 70AB>AC20==O FL>3> ;V:0@AL:>3> 70A>1C 4VBO

030;L=V V=AB@C:FVW I>4> 4>7C20==O

>;8 AC?>78B>@VW !0;>D0;L:C ?@87=0G5=V 4;O 70AB>AC20==O 3 @078 =0 4>1C, WE 22>4OBL 4>
?@O<>W :8H:8 2@0=V, 245=L V C25G5@V.

060=89 ;V:C20;L=89 @57C;LB0B <>6=0 4>AO3B8 ;8H5 ?@8 @53C;O@=>ABV9=>AC20==V
AC?>78B>@VW2 !0;>D0;L:C.

0728G09 703>AB@5==O 28@07:>2>3> :>;VBC AB8E0NBL ?@>BO3< 8-12 B86=V2.

"@820;VABL 70AB>AC20==O 287=0G0T ;V:0@.

5@54>7C20==O.

>B5?5@ ?@> 28?04:8 V=B>:A8:0FVW B0 A?5F8DVG=V 0=B84>B8 =5 ?>2V4<;O;>AL. 40=V ?@>
28?04:8 ?5@54>7C20==O (=0?@8::04, =02<8A=5 A0<>3C1AB2> 28A>:>N ?5@>@0;L=>N 4>7>N
<5A0;078=C), O:V =5 2:07CNBL =0 =8@:>2C 01> ?5GV=>2C B>:A8G=VABL. !?5F8DVG=>3> 0=B84>BC
=5 VA=CT, ;V:C20==O ?>28==> 1CB8 A8<0B8G=8< B0 ?V4B@81EV4=>ABV 70AB>A>2CNBL
2=CB@VH=L>25==C V=DC7VN 5;5:B@>;VBV2 (?@8289 4VC@57).

>1VG=V@50:FVW.

!8AB5<0 >@30=V2	'0AB>B0 2V4?>2V4=> 4> MedDRA	
	@V4:V (□ 1/10 000; □ 1/1000)	4C65 @V4:V (□ 1/10000)
!8AB5<0 :@>2V V ;V		2V (0?;0AB8G=0 0=5 F8B>7, ?0=F8B>?5=VO, =59B@>?5=VO, ;59:>?5=VO, B@> <1>F8B>?5=VO)
5@2>20 A8AB5<0	>;>2=89 1V;L, 70?0 <>@>G5==O	5@8D5@8G=0 =59@>?0BVO
!5@F52>-AC48==0 A8AB5 <0	V>:0@48B, ?5@8:0@48B	
@30=8 48E0==O, 3@C4=>W ;VB:8 B0 A5@54>ABV==O		;5@3VG=V B0 DV1@>7=V @50:FVW ;535=V2 (2.;NG0NG8 48A?=>5, :0H5;L, 1@>=E>A?07<, 0;L25>;VB, ;535=52C 5>7>=>DV;VN, V=DV;LB@0FVN ;535=V2, ?=52<>=VB, ?;52@8B)
(;C=:>2>-:8H:>289 B@0:B	14>	>AB@89 ?0=:@50B8B
8@:8		>@CH5==O DC=:FVW =8@>;, 2.;NG0NG8 3>AB@89 V E@>=VG=89 V=B5AB8=0;L=89 =5D@8B, =5D@>B8G=89 A8=4@>< V =8@:>2C =54>AB0B=VABL
(:V@0 V WW ?>EV4=V		;:>5FVO
!:5;5B=>-<O7>20 A8AB5<0 B0 A?>;CG=V B:0=8=8		V0;3VO, 0@B@0;3VO, AC4><8
		50:FVW 3V?5@GCB;82>ABV, 2.;NG0NG8 0;5@3VG=V 28A8?0==O, <548:0 <5=B>7=C 30@OG:C, A8=4@>< G5@2>=>3> 2>2G0:0, ?0=:>;VB, =01@O: 2V=:5
5GV=:0 V 6>2G=89		
5?@>4C:B82=0 A8AB5<0		;V3>A?5@1>@>B=0)
!B0=		=0;L=89 48A:>@B, 1V;L C ?@O

"0:>6 <>6;82V: 2B><0, ?0@5AB57VW, <5B35<>3;>1V=5=>A, ?>3V@H5==O A8;VBC.
5E0=V7< @>728B:C :0@48BC, ?5@8:0@48BC, ?0=:@50B8BC, =5D@8BC V 35?0B8BC C 72O7:C V7
70AB>AC20==O< <5A0;078=C =52V4><89; 2V= <>65 <0B8 0;5@3VG=C 5BV>;>3VN.
!;V4 707=0G8B8, I> 45O:V 7 F8E @>7;04V2 <>6=0 ?>OA=8B8 A0<8< 70?0;5==O< :8H5G=8:C.

"5@ABV.3 @>:8.

5 <>6=0 70AB>A>2C20B8 ?VA;O 70:V=G5==O B5@ABV, 707=0G5=>3> =0 C?0:>2FV.

#<>28 715@V30==O.

15@V30B8 C =54>ABC?=>2FV 4;O 70E8ABC 2V4 A2VB;0.

#?0:>2:0. > 5 AC?>78B>@VW2 C AB@8?V, ?> 2 AB@8?8 2 :>@>1FV 7 :0@B>=C.

0B53>@VO 2V4?CA:C. 0 @5F5?B>

8@>1=8:.

@. \$0;L: \$0@<0 <1%

VAF57=0E>465==O28@>1=8:0 B0 9>3> 04@5A0 20465==O 4VO;L=>ABV.

@. \$0;L: \$0@<0 <1%

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